Appendix D.1
Baseline Ecological Risk Assessment

Comments on Behalf of the Lower Passaic River Study Area Site Cooperating Parties Group on the Proposed Plan and Feasibility Study for the Lower Eight Miles of the Lower Passaic River Study Area Portion of the Diamond Alkali Superfund Site

I. GENERAL COMMENTS TO APPENDIX D

The focused feasibility study (FFS) ecological risk assessment (ERA) of the lower 8 miles of the lower Passaic River (LPR) (Louis Berger et al. 2014) is a conservative assessment largely reflective of a screening-level assessment that does not take into account available site-specific data, and relies frequently on assumptions that have no justification. Examples of these assumptions are presented in Table G1. U.S. Environmental Protection Agency (EPA) Region 2 has deceptively asserted that the FFS ERA is not a screening-level assessment because certain "refinements" were made between the 2007 and 2014 FFS ERAs and other assumptions were used that are "more realistic and technically defensible…to support informed decision–making" (USEPA 2014a). However, these cited "realistic" assumptions and "refinements" do not satisfy the requirements of a baseline ERA where all site-specific data are evaluated according to the purposes stated for data collection outlined in Region 2-approved work plans, and a systematic, transparent, and defensible process is used for selecting effects thresholds and exposure assumptions. In fact, the 2014 FFS ERA fails to incorporate key site-specific data (such as benthic toxicity and community data) that became available following the 2007 FFS ERA.

As a consequence of failing to perform a credible risk assessment and updating the 2007 FFS using current comprehensive site data and information, Region 2's grossly overestimated risks have resulted in overstated perceived ecological risks leading to the selection of an unnecessarily disruptive and counter-productive bank-to-bank remedy.

The implications of the inaccurate assessment of risks to the environment concluded in the FFS are significant. Contrary to the conclusion the wholesale destruction of the riverine habitat of the lower 8 miles of the Passaic River is necessary to protect ecological receptors, bank to bank removal of all sediment will result in the destruction of habitat that is functioning within the expected range of urban aquatic systems in the New York/New Jersey Harbor estuary. On the other hand, execution of a focused remedy will eliminate unacceptable exposure pathways while preserving ecological services that are to be expected in an urban estuary having significant non-chemical stressors such as high sediment total organic concentrations, periods of low dissolved oxygen concentrations, and extensive habitat modifications associated with the development of the lower portions of the Passaic River as an historical industrial center.

Region 2 has ignored the foundations of the baseline ecological risk assessment (BERA) set forth in both the LPRSA problem formulation and risk characterization plan (Windward and AECOM 2009, [in prep]). Elements related to ecological toxicity and exposure, as well as background and reference conditions established by Region 2 were ignored to generate risks that inaccurately reflect ecological impact. Furthermore, Region 2's ecological conceptual site model (CSM) is inconsistent with current site-specific data and is based on a poor understanding of exposure relationships and trophic transfer. Region 2 has failed to incorporate the urban nature of the estuarine environment of the lower 8miles.

The overly conservative and ecologically unsupported assumptions used in the FFS ERA result in risk conclusions and preliminary remediation goals (PRGs) that are unsupported, inappropriate, and misleading. The statement in the FFS ERA (Section 4.5.1, FFS Appendix D) that "the results of the uncertainty analysis indicate that the overall assumptions are reasonable and appropriate for characterizing risks to the ecological receptors" is entirely unfounded. If Region 2 had implemented their

approved problem formulation and revised risk characterization plan that the Cooperating Parties Group (CPG) used to conduct the BERA, these uncertainties would have been effectively managed, thereby producing a more reliable assessment of risk. The majority of the selected toxicity thresholds and the use of "generic" fish to derive HQs are not "reasonable and appropriate" assumptions. Generic sediment thresholds used to derive hazard quotients (HQs) up to 200 for benthic invertebrates are inaccurate at predicting site-specific toxicity. In addition, a large number of the toxicity studies used to derive HQs are not appropriate for establishing baseline risk thresholds; HQs of 1,000 were estimated for 2,3,7,8-tetrachlorodibenzo-*p*-dioxin (2,3,7,8-TCDD) in sediment for benthic invertebrates based on an technically indefensible derived threshold (Kubiak et al. 2007). HQs for fish, birds, and mammals based on the use of "generic" fish to derive exposure estimates are misleading and overstate risks based on the inaccurate assumption that all fish species, including freshwater fish, occur throughout the FFS Study Area and that wildlife can prey on all fish, regardless of size. The following general comments provide the justification for the need to develop a more appropriate ERA for informing remedial action and are discussed in greater detail below:

A. The benthic invertebrate community risk assessment conducted in the FFS is equivalent to a screening-level risk assessment because it uses generic sediment thresholds and ignores site-specific sediment toxicity and benthic community data. This highlights the disparity between the FSS ERA and CPG's LPRSA BERA where data collected under the direction of Region 2 were omitted in the FSS ERA. This has resulted in a gross overstatement of risks to the benthic community, unnecessarily low PRGs, and subsequently an incorrect selection of a bank-to-bank remedy. The site-specific benthic data that were wholly disregarded in the FFS ERA were collected in accordance with EPA's risk assessment process (USEPA 1997) using planning documents and a quality assurance project plan (QAPP) approval process in order to accurately characterize site-specific benthic risks.

B. The assessment of fish and wildlife risks in the FFS relies on screening-level assumptions (i.e., generic exposure assumptions not supported by ecological or site-specific data and inappropriate and technically indefensible toxicity thresholds) resulting in misleading HQs that overstate risks to fish and wildlife. In turn, this has resulted in unrealistically low PRGs and the subsequent selection of an unnecessary remedy.

C. The FFS ecological conceptual site model (CSM) has not changed from the 2007 FFS despite the fact that more recent site-specific data have become available. The FFS ecological CSM is overly simplistic and inconsistent with the ecology of the LPR resulting in a poor understanding of exposure relationships and trophic transfer. The failure to better understand the LPR has resulted in faulty risk conclusions and a skewed value of the preferred remedial alternative relative to other alternatives which has led to an unnecessary remedy. Region 2 needs to assess the current site-specific information to understand the actual abiotic-biotic relationships in the river, which will lead to a better-informed remedy selection process.

Table G1. Comparison of SLERA, Region 2 FFS ERA, and CPG LPRSA BERA Methods

General SLERA Methods	Region 2 FFS ERA	CPG LPRSA BERA
Toxicological benchmarks		
Use generic thresholds	For characterizing benthic risks, used only generic sediment quality values equivalent to screening values and ignored site-specific LPR sediment benthic toxicity tests and community data collected for characterizing benthic risks per the Region 2-approved Benthic QAPP (Windward 2009b) and LPRSA PFD (Windward and AECOM 2009).	For characterizing benthic risks, used site-specific sediment quality triad (SQT) data

General SLERA Methods	Region 2 FFS ERA	CPG LPRSA BERA
Use literature-based thresholds	Misleadingly cited two studies as "site-specific" to derive technically indefensible invertebrate 2,3,7,8-TCDD CBRs and sediment thresholds that are wholly inappropriate for informing remedial decisions.	Used site-specific data, when available (e.g., LPR benthic and ecological survey data)
Use easily available generic literature-based thresholds	Provided no rationale or specific criteria used to select baseline CBRs/TRVs resulting in inappropriate CBRs/TRVs for determining baseline risks	Used refined TRVs based on thorough review and systematic evaluation of primary literature with transparent TRV selection process documented
Exposure concentrations and doses		
Based on maximum values	Based on UCL concentrations; however, the derivation of UCLs is not transparent in some cases, and UCLs do not accurately represent the current data set and ecology (e.g., use of "generic fish").	Based on UCLs representative of LPR ecology
Based on limited site-specific or modeled data	Used site-specific tissue data; however, omitted site-specific data collected with the intent of characterizing baseline risks in the LPRSA, including site-specific benthic toxicity and community data, lipid data (for egg modeling parameters), and additional sediment data.	Based on all available site-specific data, including benthic, LPR egg lipid, and complete sediment data sets
Based on generic exposure assumptions	Used "generic fish" as prey for birds and mammals, an assumption that is not ecologically accurate.	Based on ecologically supported assumptions
Problem formulation		
Based on generic receptors	Included carp as part of the "generic fish" to evaluate risk to fish populations, disregarding the presence of invasive carp as ecologically detrimental.	Based on site-appropriate receptors following the PFD and risk characterization plans
Spatially explicit exposures		
No use of spatially explicit exposures	Evaluated mudflat areas for specific receptors, but did not account for ecologically supported differences in fish exposure areas based on salinity tolerance and mammal exposure areas based on actual utilization of habitat.	Used spatially explicit exposures based on LPR ecology and receptor-specific life history
Risk assessment outcome		
Derive COPEC list based on HQs > 1.0	Generalized risk conclusions for informing cleanup levels based on HQs > 1.0 without discussion of population- or community-level risk and without evaluation of multiple lines of evidence (LOEs) (e.g., diet and egg LOEs).	Included discussion of population- and community-level risks and discussion of multiple LOEs
Derive COPEC list based on limited number of LOEs	For characterizing benthic risks, failed to conduct an SQT analysis, which should have included a comparison to reference area information per the Region 2-approved Benthic QAPP (Windward 2009b) and LPRSA PFD (Windward and AECOM 2009).	Determined benthic risk conclusions based on a weight-of-evidence (WOE) approach of the SQT data

The following briefing provides the arguments and facts to support each of the three general comments listed above.

A. The benthic invertebrate community risk assessment conducted in the FFS is equivalent to a screening-level risk assessment because it uses generic sediment thresholds and ignores site-specific sediment toxicity and benthic community data. This highlights the disparity between the FSS ERA and CPG's LPRSA BERA where data collected under the direction of Region 2 were omitted in the FSS ERA. This has resulted in a gross overstatement of risks to the benthic community, unnecessarily low PRGs, and subsequently an incorrect selection of a bank-to-bank remedy. The site-specific benthic data that were wholly disregarded in the FFS ERA were collected in accordance with EPA's risk assessment process (USEPA 1997) using planning documents and a QAPP approval process in order to accurately characterize site-specific benthic risks.

The FFS ERA presents only a cursory, screening-level assessment of risks to the benthic community, resulting in an overestimate of risks posed by exposure to sediment in the FFS study area (the lower 8.3 miles of the Passaic River). The FFS ERA also ignores site-specific data and plans (collected under Region 2-approved planning documents and QAPPs for the LPRSA), which further biases the resulting PRG development and remedy selection. The National Remedy Review Board's Contaminated Sediments Technical Advisory Group letter (dated April 11, 2014) states "the FFS ecological risk assessment [FFS ERA] is largely a conservative, literature-based FFS ERA" (USEPA 2014b). This is inconsistent with EPA guidance, which states the risk assessment should refine the COPECs after the screening ERA using a work plan and field verification process (which was completed and approved for LPRSA, and subsequently ignored for the FFS) to develop a site-specific risk estimate (USEPA 1997). In addition, the FFS ignores the multi-million-dollar site-specific sampling, analysis, and planning documents developed for the LPRSA. Planning documents such as the Region 2 Problem Formulation Document (PFD) (Windward and AECOM 2009), the Revised Risk Analysis and Characterization (Windward and AECOM [in prep]), and the site-related QAPPs and reports (see Table 1 of the specific comments) were either ignored or replaced by ecologically irrelevant assumptions in the FFS. Use of these planning documents, site-specific data, and ecologically relevant assumptions will lead to a more informed remedy, one that is based on appropriate PRGs, uses site-specific information, and is consistent with EPA guidelines.

The FFS ERA compares surface sediment chemistry data to generic sediment quality guideline values based on the Effects Range-Median (ER-M) approach and results of a logistic regression model (LRM), which do not represent a valid approach to determining the need for remediation.[1] Region 2 misleadingly indicates in Attachment 1.3 of the FFS Appendix D that the "sediment benchmark selection process was substantially revised [from the 2007 FFS ERA]" to address "the low level of confidence associated with some of the ER-L [effects range-low] values…and the lack of bounding risk estimates". Of the nine COPECs, four of the sediment values are the same between the 2007 and 2014 FFS ERAs (low-molecular weight polycyclic aromatic hydrocarbons [LPAHs], high-molecular weight polycyclic aromatic hydrocarbons [HPAHs], DDx, and 2,3,7,8-TCDD lower end thresholds are based on ER-Ls). The other five COPECs had revised values based on the T20/T50 values from the LRM; however, the lower bound values used in the 2014 FFS ERA for three of these COPECs (copper, lead, and mercury) are actually lower than the ER-L values used in the 2007 FFS which were cited to be unreliable at predicting toxicity.

Multiple authorities and researchers caution against simply applying generic sediment quality guideline values to define risks to the benthic community:

- USEPA (2005b) states that LRMs should not be considered a complete substitute for direct-effects assessment (e.g., toxicity tests).
- NJDEP (2012) states that ecological evaluation of sediment contamination should consider background concentrations relevant to urban conditions. The comparison of sediment chemistry data to New Jersey Department of Environmental Protection (NJDEP) ecological screening

[1] In addition, USEPA provides a sediment benchmark for 2,3,7,8-TCDD that is said to be site specific. However, although the data for this sediment benchmark was generated regionally, it was not specific to the FFS study area or even the Passaic River. The inappropriateness of promulgating this sediment benchmark is discussed in detail in Comment B.

criteria, which are not promulgated standards, is intended as a screening-level evaluation, preliminary to further comparison to background.

- NYSDEC (2013) considers sediment quality guidelines (SQGs) a conservative tool for making an initial assessment of the potential risks that might be associated with contaminants in a sediment sample.
- Ed Long, the developer of the ER-M approach, states in Long et al. (1998) that ER-Ms are not intended to represent effects thresholds above which adverse effects would always be observed, but should rather be used at sites to estimate the potential for adverse biological damage. ERAs of sediments are most comprehensive when all three components of the sediment quality triad (SQT) are included in the approach. Long states that SQGs should be used in conjunction with other tools within an integrated framework for assessing sediment quality.
- Long et al. (2006) states that SQGs should be included with other measures, including the results of toxicity tests and benthic community surveys, to provide a weight-of-evidence (WOE) when assessing the relative quality of contaminated sediments.
- In addition, NOAA (1999) states that SQGs were developed as informal, interpretive tools for the National Status and Trends Program to rank areas that warranted further detailed study of the actual occurrence of adverse effects such as toxicity. The SQGs were not promulgated as regulatory criteria or standards, but were intended as informal (non-regulatory) guidelines for use in interpreting sediment chemistry data. Toxicity must be confirmed with empirical data from toxicity tests.
- Sediment criteria values such as the ER-M and the LRM have been identified by several authors (O'Connor 2004; O'Connor et al. 1998; Wetherington et al. 2005) as useful for screening purposes, but inappropriate or inaccurate for characterizing benthic community risk. Specifically, Wetherington et al. (2005) showed that the LRM resulted in a false positive rate of 55% when applied to EPA's National Sediment Inventory database. O'Connor (2004) noted that effects-range sediment quality values, which are not predictive of toxicity, are inappropriate for use in the characterization of risk. O'Connor et al. (1998) note that the ER-M accurately predicted toxicity in only 38% of sediment samples (n = 1,508); O'Connor et al. (1998) suggest that the ER-M be used to identify samples for further examination, and that biological data (e.g., toxicity and benthic community data) be evaluated at the same time as co-occurring sediment chemistry (Adams et al. 1992).

The approach used for the FFS is identical to that used for the screening-level ecological risk assessment (SLERA) that Region 2 required CPG to conduct as part of the site-wide remedial investigation/feasibility study (RI/FS) (Windward and AECOM 2009, [in prep]). The sole purpose of the SLERA is to tentatively identify chemicals of potential ecological concern (COPECs) that would be considered in the BERA. EPA ecological risk assessment guidance is clear that a SLERA is neither designed nor intended to provide definitive estimates of actual risk or generate cleanup goals, as it is not based on site-specific assumptions (USEPA 2001). The purpose of a SLERA is to assess the need and, if required, the level of effort necessary, to conduct a baseline risk assessment. For the LPRSA site-wide RI/FS, Region 2 (Windward and AECOM 2009, [in prep]) determined that the appropriate way to assess baseline risks to the benthic community would be to conduct a comprehensive sediment SQT, which would include a comparison of LPR benthic community and toxicity response data to similar data from a reference area. This comparison would be used to define benthic community conditions and toxicity test responses associated with general conditions in an urbanized environment. Region 2, with input from the Partner Agencies, directed CPG as to which reference areas and reference data should be used for the comparison. The disregard for the use of reference data in the FFS speaks to the lack of consistency and disregard for the LPRSA ERA process exercised by Region 2 in the FFS ERA.

The use of a WOE approach based on SQT data is a standard method for assessing baseline risks:

- NJDEP (2012) requires that the evaluation of sediment quality follow the SQT paradigm, in that sediment chemistry, sediment toxicity, and benthic community data must be evaluated using a WOE approach.
- USEPA (1999) provides clear guidance for risk managers on the use of field data, stating, "The baseline risk assessment may include site-specific toxicity tests with test organisms that address the endpoints selected for the site. Through the use of field studies and/or toxicity tests, several types of data may be developed to provide supporting information for a lines-of-evidence approach to characterizing site risks. This approach is far superior to using single studies or tests or measurements to determine whether or not the observed or predicted risk is unacceptable."
- Chapman (2002) states that there is general agreement in the scientific community that toxicity cannot be defined solely on the basis of chemistry: "Toxicity as an ecological response is best measured directly."
- Ingersoll et al. (2005) summarize the large number of published studies that have evaluated the ability of SQGs to predict effects observed in laboratory toxicity tests or in field studies of benthic communities. The authors conclude that whenever possible, decisions regarding the management of contaminated sediments should be made using a WOE approach.

An SQT analysis for the Passaic River has been completed by the CPG using an approach approved by Region 2 and is presented in the draft BERA (2014). All of the site-specific data from the lower 8.3 miles of the Passaic River used in the BERA (2014) were presented to Region 2 in multiple documents (Windward 2014a, [in prep]-k, a) and were known to Region 2 during development of the FFS ERA (as evidenced by inclusion in the FFS of the surface sediment chemistry data from the site-specific data reports produced by the CPG). If the FFS ERA had conducted an SQT analysis using the Region 2-approved CPG-generated SQT data, instead of conducting merely a simple screening-level assessment by comparing surface sediment chemistry data to generic sediment quality values, the FFS would have arrived at a far different conclusion concerning potential risks to the benthic community. In stark contrast to the conclusions of the FFS ERA, the following is a summary of key findings of the SQT analysis conducted in a similar manner to the BERA but specific to the lower 8.3 miles of the Passaic River:

- **Benthic community metrics**: Benthic community metrics for the FFS study area were compared to benthic community metric data from Jamaica Bay, a reference area for the estuarine portion of the Passaic River that Region 2 directed the CPG to use in the BERA for defining risks to the benthic community. Of the 49 locations in the lower 8.3 miles of the Passaic River from which estuarine benthic community data were collected in 2009, only 2 locations exhibited benthic community metrics different from those in the Jamaica Bay reference area. The data from the two locations, one at river mile (RM) 5 and the other at RM 7, were only different from the reference data for a limited number of benthic community metrics. Benthic community metrics from all other estuarine locations in the lower Passaic River were within the range of conditions observed in the Jamaica Bay data.
- **Toxicity test response data:** Toxicity test data for samples collected in the estuarine portion of the lower 8.3 miles of the Passaic River were similar to toxicity response data from Jamaica Bay. Of the 27 locations sampled in 2009 with toxicity test data for *Ampelisca abdita* survival, only 2 locations exhibited reduced *A. abdita* survival compared with *A. abdita* data from the Jamaica Bay reference area. The two locations were highly localized (e.g., immediately above RM 3.5) and not representative of the entire 8.3 miles. All other estuarine locations sampled in the lower Passaic River exhibited toxicity responses that were within the range of toxicity responses observed in Jamaica Bay data.
- **Sediment chemistry**: As noted earlier in this comment, sediment quality guideline values should not be used for purposes other than conducting a screening analysis of the data. Wetherington et al. (2005) and O'Connor et al. (1998), among others, have demonstrated that ER-Ms are highly unreliable (e.g., have high false positive rates) for predicting the toxicity of chemicals in sediment. An analysis of the reliability of the sediment benchmarks presented in the FFS for correctly predicting toxicity in the FFS study area relative to reference conditions (Table G2) demonstrates

that the sediment quality guideline values used in the FFS ERA to define risks to the benthic community only correctly predicted toxicity between 7% and 12% of the time. These results demonstrate that sediment chemistry alone (based on comparison to generic sediment quality guideline values) is not a reliable determinant of potential risks to the benthic community. Even when sediment chemistry data are used in conjunction with more direct measures of potential risks to the benthic community (i.e., benthic community metrics and sediment toxicity test data), it does not provide confirmation of the observations made using the direct measures.

As would be expected given its physical setting, the benthic community structure in the LPRSA is generally consistent with urban reference conditions. A comparison of LPRSA benthic community metrics with the reference data indicates that the benthic community in the estuarine and transitional salinity zones (typical of the lower 8 miles) exhibit few differences when compared with other urban, less contaminated estuaries indicating that the LPRSA benthic community is responding to typical urban stresses.

Table G2. Reliability of FFS Sediment Screening Criteria for Predicting Toxicity for *A. abdita* Survival

Chemical	Unit	Low Screening Criteria[a]		High Screening Criteria[a]	
		Value	Positive Predictive Power[b]	Value	Positive Predictive Power[b]
Copper	mg/kg	94	7.7 %	32	8.3 %
Lead	mg/kg	94	7.4 %	30	8.3 %
Mercury	µg/kg	480	7.7 %	140	7.7 %
Total HPAHs	µg/kg	9,600	7.4 %	1700	7.7 %
Total LPAHs	µg/kg	3,200	7.4 %	550	11.8 %
Total PCB congeners	µg/kg	370	7.7 %	35	8.0 %
2,3,7,8-TCDD	ng/kg	3.2	7.4 %	na	8.0 %
Dieldrin	µg/kg	2.9	8.0 %	0.83	10.5 %
Total DDx	µg/kg	46	7.4 %	1.6	8.0 %

Note: Analysis based on 27 locations below RM 8.3 that were considered estuarine during the 2009 RI/FS sampling (i.e., salinity < 0.5 ppt), and for which the *A. abdita* 10-day survival test was conducted. Test results were compared with reference area data from Jamaica Bay.

DDD = dichlorodiphenyldichloroethane
DDE = dichlorodiphenyldichloroethylene
DDT = dichlorodiphenyltrichloroethane
FFS = focused feasibility study
HPAH = high-molecular-weight polycyclic aromatic hydrocarbon
LPAH = low-molecular-weight polycyclic aromatic hydrocarbon
PCB = polychlorinated biphenyl
ppt = parts per thousand
RI/FS = remedial investigation/feasibility study
RM = river mile
TCDD = tetrachlorodibenzo-*p*-dioxin
total DDx = sum of all six DDT isomers (2,4′-DDD, 4,4′-DDD, 2,4′-DDE, 4,4′-DDE, 2,4′-DDT and 4,4′-DDT)

[a] As cited in the FFS, Table 4-12.

[b] The positive predictive power is calculated as the number of correctly predicted results divided by the number of samples predicted to be toxic using the sediment benchmarks presented in the FFS.

The results of the SQT analysis for the lower 8.3 miles using the SQT data generated by the CPG from Region 2-approved QAPPs, show that the impacts to the benthic community are limited to localized areas of the estuarine portion of the LPR. Of all the SQT locations within the lower 8.3 miles, only a small subset shows a moderate likelihood for benthic impact as compared with reference conditions; as discussed in CPG's BERA, these impacts are not directly related to chemistry. If the FFS had implemented an SQT analysis that evaluated the benthic data types listed in the Region 2-approved problem formulation rather than conducting a simple screening-level assessment, it would have arrived at a far different conclusion concerning potential risks to the benthic community. In stark contrast to the proposed bank-to-bank remedy, the SQT analysis would have confirmed the efficacy of a targeted approach.

B. The assessment of fish and wildlife risks in the FFS relies on screening-level type assumptions (i.e., generic exposure assumptions not supported by ecological or site-specific data and inappropriate and technically indefensible toxicity thresholds) resulting in misleading HQs that overstate risks to fish and wildlife. In turn, this has resulted in unrealistically low PRGs and the subsequent selection of an unnecessary remedy.

The FFS fish and wildlife assessments include a variety of screening-level type assumptions, including:

- The grossly oversimplified use of "generic fish" (an artificial "composite" of available fish tissue excluding mummichog) for evaluating risks to all fish (without taking into account the occurrence of fish species within the FFS study area) and fish-eating birds and mammals (without taking into account realistic assumptions about prey size)
- The use of toxicity thresholds that are the basis for determining HQs and PRGs without justification or basis for selection
- The use of generic assumptions (rather than site-specific and receptor-specific data) for modeling egg concentrations and regarding habitat use in the FFS study area

The use of these unsupportable assumptions results in misleading HQs that overstate ecological risks.

1. <u>The use of "generic fish" is inappropriate, inaccurate, and misleading for the evaluation of potential risks to fish and wildlife.</u>

The FFS consolidated all fish species (other than mummichog) into a single "generic fish," regardless of size, feeding guild, or exposure area. The "generic fish" combined fish species that ranged several orders in magnitude in size; median mass reported for fish analytical samples included in the "generic fish" ranged from 79 to 3,044 g. The tissue concentrations of the "generic fish" were used to assess risks to fish from exposure to hazardous substances, and were also used as a source of food in determining risks to fish-consuming mammals and birds. Region 2, in deciding to construct a "generic fish," disregarded the species-specific data collected from the LPR. While the intent may have been to construct a single fish tissue concentration to be used in the ERA to make the analysis simpler, comingling the various species diminished the ability of Region 2 risk assessors to properly identify risks associated with specific fish species or trophic relationships for species that consume fish.

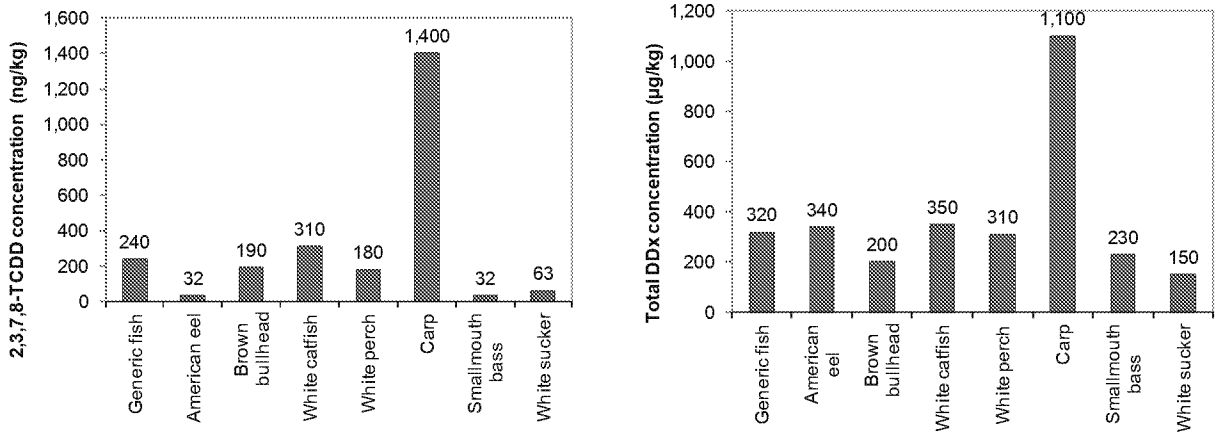
The calculation of HQs across fish species and feeding guilds for the derivation of fish HQs is misleading and inappropriate. Contaminant levels vary among species with different feeding habits; thus, three general feeding guilds were selected for evaluation of potential risks to fish in the Region 2-approved PFD (Windward and AECOM 2009): benthic omnivores, invertivores, and piscivores. The FFS "generic fish" is constructed from seven fish species from these three feeding guilds, each of which represents a different exposure history based on feeding strategy resulting in varying tissue concentrations. In fact, median fish tissue concentrations for bioaccumulative chemicals of interest varied by an order of magnitude (Table G3). Figure G1 illustrates the large differences in concentrations for several chemicals in carp samples compared to other fish samples.

By pooling the tissue concentration data across fish species for the calculation of exposure point concentrations (EPCs), Region 2 assumes that the tissue concentration data come from statistically similar populations (i.e., equal means and variances in the tissue concentrations of all species). However, based on the tissue concentrations in carp relative to other species, this statistical assumption is clearly violated and so the EPC calculations are wrong. For example, tissue concentrations in carp are clearly higher than the tissue concentrations in other species, and are particularly higher than in tissue concentrations in the small fish that are prey species. The elimination of carp tissue data (as well as data from other large [>30 cm] or predominately freshwater species) is necessary to correct Region 2's statistical error and also would provide an ecologically relevant fish tissue EPC, which Region 2's EPC does not.

Table G3. Median concentration of bioaccumulative chemicals in fish from the FFS Study Area

Chemical	American eel	Brown bullhead	Carp	Small-mouth bass	White catfish	White perch	White sucker
Mercury (µg/kg)	275	54	49	180	250	135	120
Dieldrin (µg/kg)	40	33	50	20	16	26	19
Total DDx (µg/kg)	290	195	545	230	220	225	150
Total PCBs (µg/kg)	1,850	1,650	3,950	630	3,200	2,400	1,400
Dioxin TEQ-Fish (ng/kg)	28	185	445	33	220	170	64
PCB TEQ-Fish (ng/kg)	11	5.9	14	2.7	15	8.0	5.7
Total TEQ-Fish (ng/kg)	36	190	460	36	235	175	72
2,3,7,8-TCDD (ng/kg)	26	175	430	32	210	160	63

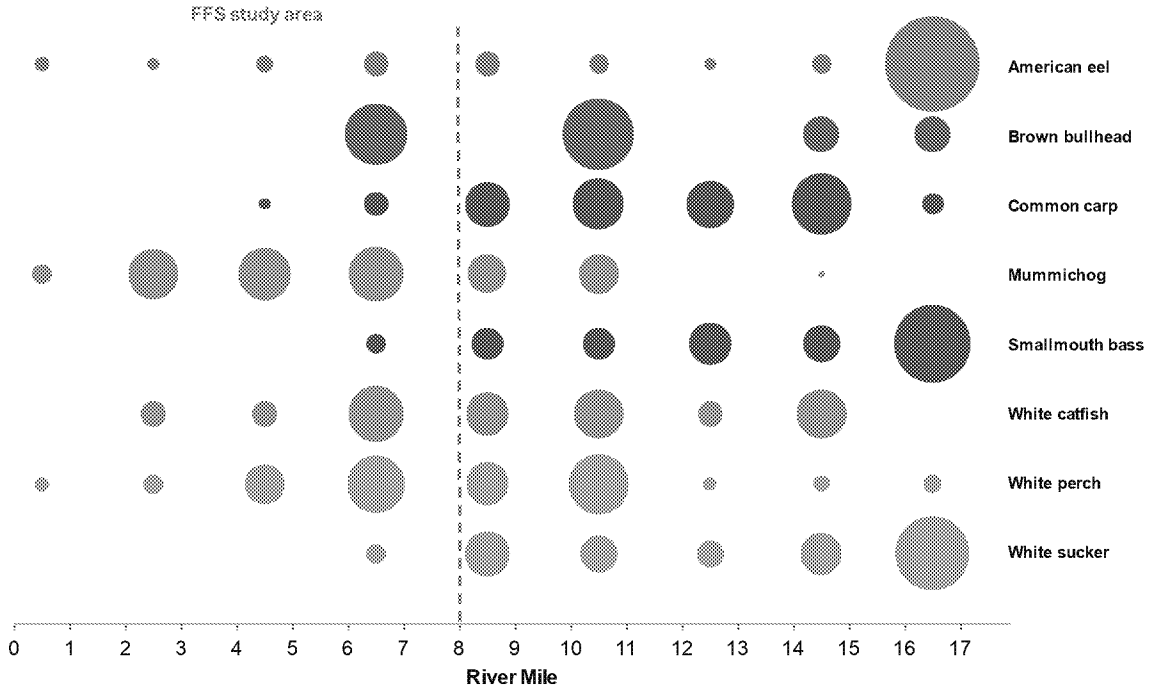
DDD = dichlorodiphenyldichloroethane
DDE = dichlorodiphenyldichloroethylene
DDT = dichlorodiphenyltrichloroethane
FFS = focused feasibility study
PCB = polychlorinated biphenyl
TCDD = tetrachlorodibenzo-*p*-dioxin
TEQ = toxic equivalent
total DDx = sum of all six DDT isomers (2,4′-DDD, 4,4′-DDD, 2,4′-DDE, 4,4′-DDE, 2,4′-DDT and 4,4′-DDT)



Note: All concentrations calculated as the UCL (or maximum concentration where sample size is too small to calculate a UCL).

Figure G1. Comparison of Example Tissue EPCs between Individual Fish Species

The exposure areas of the seven species of fish differ based on factors such as salinity tolerance, which acts as a barrier to movement to the lower portions of the river for freshwater species. As a result, the tissue concentration of the "generic fish" does not represent exposure throughout the lower 8.3 miles of the LPR and is ecologically incorrect. For example, carp, the species with the highest concentrations for a number of key contaminants across all fish species collected in the LPR, were only found above RM 5 and by far the largest number of carp was collected above RM 8 (Figure G2). The inclusion of carp in a "generic fish" overstates fish tissue concentrations of key contaminants for other species in the lower 8.3 miles of the Passaic River. Smallmouth bass and white sucker, also included in the "generic fish," were only collected above RM 7 and do not reflect an exposure to the lower 8.3 miles of the LPR. An EPC based on "generic fish" is both statistically incorrect and does not represent the ecology of the lower eight miles of the LPR.



Note: Actual location of fish catch was rounded to the nearest river mile; the area of each bubble represents the percentage of each fish species caught per river mile.

Figure G2. Relative Percentages of Fish Species Caught per River Mile in the LPRSA

The calculation of HQs for birds and mammals using the "generic" fish data is also misleading and inaccurate. Fish-eating birds and mammals are limited in the size of fish they can prey on, and most of the fish used to construct the "generic fish" exceed the size limit (Figures G3 and G4). Large fish, such as carp, are not a realistic food source for birds and mammals, so the use of "generic fish" to derive HQs results in unrealistically high exposure concentrations. The use of the "generic fish" to derive HQs is inappropriate and scientifically unsound for an assessment of risk posed to mammals and avian species utilizing the lower 8.3 miles of the Passaic River.

For the great blue heron, only a fraction of the individual white perch analyzed from the lower 8.3 miles of the Passaic River were of suitable size for consumption (estimated to be approximately 13 cm; see specific comments); no perch composite samples included only fish ≤ 13 cm long. In fact, the only species that met the prey size requirements for the great blue heron (i.e., all fish in each composite were less than the appropriate prey size) was mummichog.

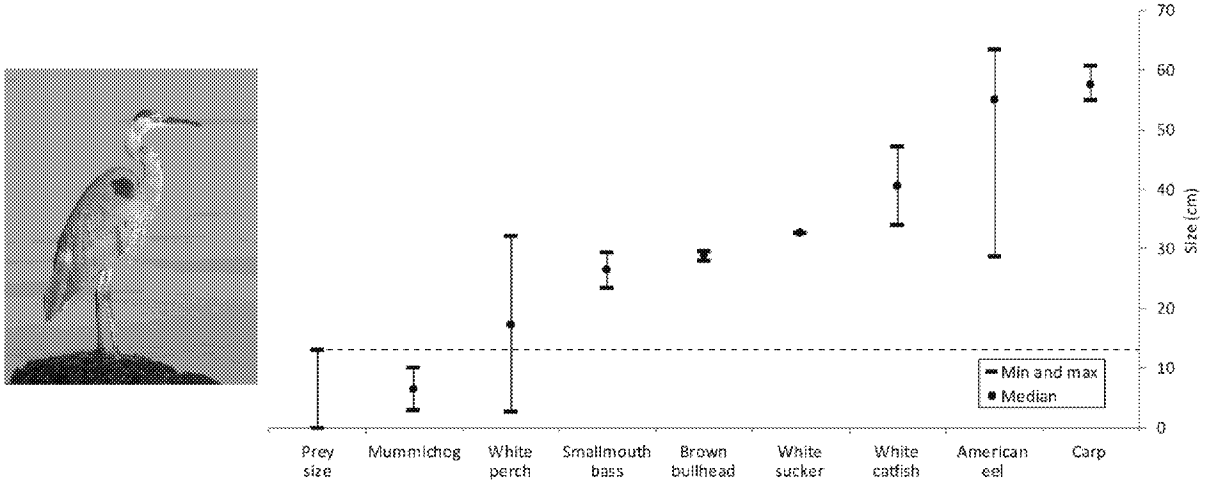


Figure G3. Heron Prey Size Compared to Samples Collected from the FFS Study Area

For mink, only a limited portion of the size range of a single fish species included in the "generic fish" were based on individual fish within the size range suitable for consumption (estimated to be approximately 30 cm; see specific comments). Only the following fish species from the "generic fish" category met the prey size requirement for mink (i.e., all fish in each composite were less than the appropriate prey size): brown bullhead, smallmouth bass, and white perch. Mummichog should also have been included in the fish portion of the mink diet, as mummichog represent appropriately sized prey that are abundant in the LPR, but were not included in the FFS mink diet.

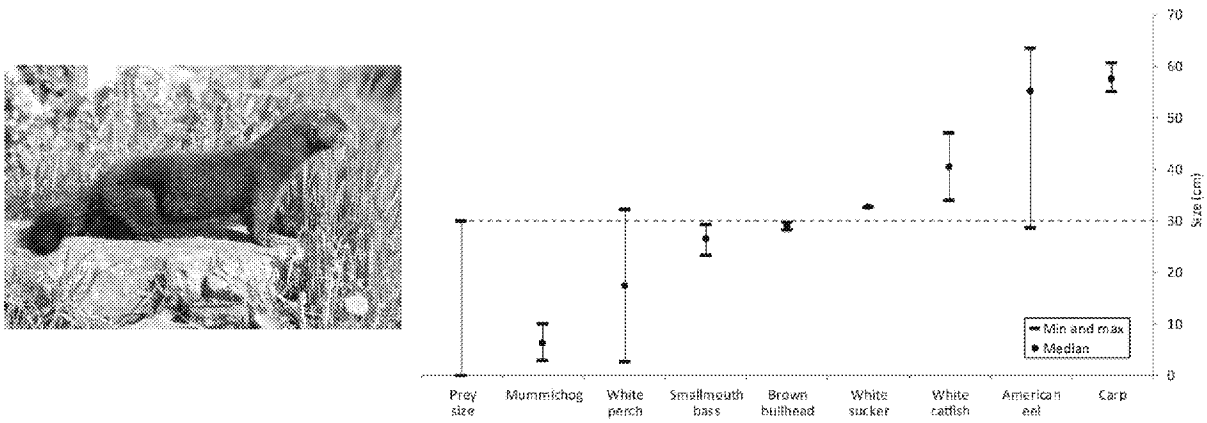


Figure G4. Mink Prey Size Compared to Samples Collected from the FFS Study Area

Figure G5 shows a comparison of UCLs based on "generic fish" to UCLs based on appropriately-sized fish and illustrate how the 'generic fish" UCL overstates exposure and risks to birds and mammals, especially for key bioaccumulative chemicals.

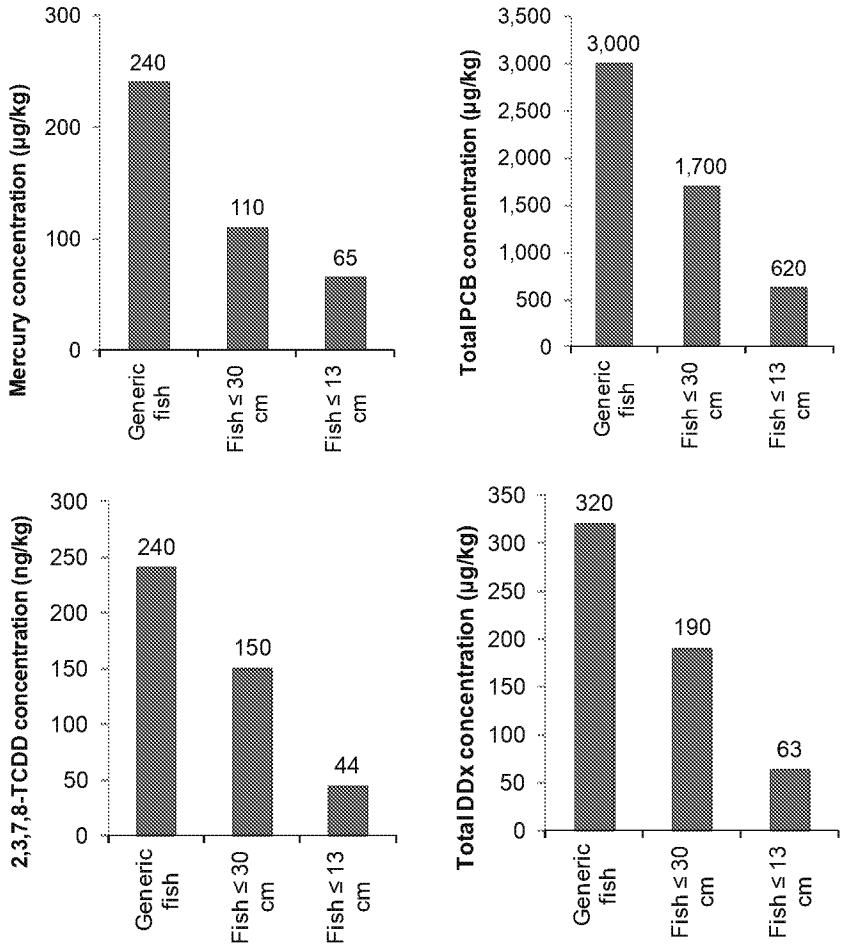


Figure G5. Comparison of UCLs of the FFS "Generic" Fish to Those Based on Size-appropriate Prey for Heron (Fish ≤13 cm) and River Otter (Fish ≤30 cm)

2. The FFS uses inappropriate and technically indefensible toxicity thresholds without justification or basis for selection

The majority of the selected critical body residues (CBRs) and toxicity reference values (TRVs) used in the FFS ERA are not appropriate for the evaluation of baseline risks for the site (see General Comment A regarding the sediment thresholds used for invertebrates). No rationale or specific criteria used to select FFS ERA CBRs and TRVs are provided other than the following text from Attachment 1.3, which states that, "*In this 2013 BERA, a more rigorous evaluation of the literature was conducted, including consideration and selection, in some cases, of toxicological endpoints that were not strictly based on survival, growth or reproductive effects. However, the final set of CBRs and toxicity reference values (TRVs) that derived from a consensus-based review process with Partner Agencies was determined to be more relevant to the objectives of the BERA than the 2007 benchmark set*". The details of that "more rigorous evaluation" and "consensus-based review process" and the justification to include additional endpoints other than specified assessment endpoints (growth, survival, and reproduction) are not provided (e.g., studies reviewed, rationale for TRV selection). In fact, several of the TRVs selected for the current 2014 FFS ERA (i.e., invertebrate CBRs for dieldrin, mercury TRVs for bird diet, mercury TRVs for mammal diet) are based on the same studies as the 2007 FFS ERA; however, the current 2014 TRVs are lower because extrapolation factors (EFs) have been applied (without thorough justification) to the original TRVs used in the 2007 FFS ERA. The TRVs presented in CPG's LPRSA BERA represent an appropriate set of toxicological thresholds for use in a baseline assessment that are actually based on a rigorous evaluation of the data. CPG's TRVs are based on an extensive search and systematic review of primary

toxicological literature, and were selected using a transparent selection process that is documented in the LPRSA BERA.

Furthermore, uncertainties associated with a number of the CBR/TRVs suggest that they are inappropriate for use in a baseline risk assessment (see specific TRV comments), but the uncertainty discussion of TRVs in Appendix D is inadequate for a baseline risk assessment.

As an example, the FFS ERA and Region 2's responses to recent National Remedy Review Board's Contaminated Sediments Technical Advisory Group comments on the FFS (USEPA 2014b) misleadingly cite a study performed by Wintermyer and Cooper (2003) and "tabulated" by the US Fish and Wildlife Service (USFWS) (Kubiak et al. 2007) as site-specific and "most appropriate for FFS remedial decision-making." The use of this single, non-replicated study has led Region 2 to derive technically indefensible and unreliable invertebrate 2,3,7,8-TCDD CBRs and sediment thresholds that are wholly inappropriate for informing remedial decisions. This study results in the lowest sediment and tissue PRGs across all ecological receptors for 2,3,7,8-TCDD.

Tissue CBRs were derived from Wintermyer and Cooper (2003), wherein concentrations of PCBs and dioxins/furans were measured in oysters deployed at two locations near Newark Bay: one in Arthur Kill (Newark Bay estuary) and the other at Sandy Hook, New Jersey. The study appears to have based its conclusions on a single tissue sample (a composite of seven oysters) from each of the two sites. In the study, reproductive effects were evaluated by measuring the success rate of egg fertilization from a subset of the transplanted oysters and of normal early development (48 hours) of those fertilized eggs in a single test. This study, based on one sample (n = 1), does not provide any measure of variability in tissue concentrations, and no evidence is provided indicating that the findings are reproducible.

The sediment threshold for 2,3,7,8-TCDD was derived by USFWS (Kubiak et al. 2007) by poorly pairing the two tissue values for transplanted oysters reported in Wintermyer and Cooper (2003) (one from Arthur Kill and the other from Sandy Hook) with sediment data collected for the Contaminant Assessment and Reduction Program (CARP). The sediment threshold was back-calculated by Kubiak et al. (2007) from the tissue concentrations by applying a biota-sediment accumulation factor (BSAF) that was calculated using only those same two tissue concentrations.

BSAFs were calculated contrary to EPA methodology and guidelines for developing BSAFs (Burkhard 2009), which stress the importance of using data with similar underlying conditions (both ecological and chemical). According to EPA, "*mixing of C_{soc}-C_l* (sediment and tissue) *paired observations with different underlying conditions is not recommended and will, in all likelihood, result in BSAFs with poor predictive accuracy*." Judd et al. (2013) evaluated a large BSAF data set from EPA's Mid-Continent Ecology Division and demonstrated that biota-sediment relationships cannot be assumed to be linear, and that basing decisions on BSAFs focused on one chemical is highly uncertain. The use of only two paired observations to develop a sediment benchmark (and ultimately a cleanup goal) for a single chemical is not defensible.

Clearly, in addition to the tissue thresholds being inappropriate for use as effect and no-effect thresholds (see above), the methods used by USFWS in the back-calculation misapplied the available data (i.e., using tissue and sediment data collected independently [i.e., not co-located] and for other purposes and combining them as pairs to calculate BSAFs). A single sediment sample collected from Arthur Kill was paired with one tissue sample result from a single location an unknown distance from where oysters were exposed (Wintermyer and Cooper 2003) to derive a BSAF. The sediment was not co-located with the tissue data and was from one sediment sample, failing to provide an indication of the variability in chemical concentrations. It appears a BSAF was also calculated for Sandy Hook, but the location of the "co-located "sediment used to derive this BSAF is not even provided.

In summary, the tissue CBR and sediment benchmark values for 2,3,7,8-TCDD were derived using methods that are not based on sound scientific methodology. The approach presented in the FFS ERA is not scientifically valid because:

- Combining non-paired oyster tissue and sediment chemistry data (i.e., data collected as part of different studies) to establish a cause and effect relationship is not generally accepted in the scientific community as an appropriate method.
- Error rates cannot be established for the tissue CBR and sediment benchmark or resulting PRGs because the methods rely on extremely limited data that consist of a single oyster tissue sample (n=1) with no replication within the study and a single sediment sample.
- The sediment benchmark for 2,3,7,8-TCDD is based on the results of a non-peer reviewed analysis (i.e., a conference presentation).

Interestingly, the sediment PRG for 2,3,7,8-TCDD proposed in the FFS that is intended to provide a protective level for invertebrates affected adversely from sediment concentrations derived from this calculation (3 ppt dw) is similar to the background values reported from Mullica River/Great Bay, an area considered by Region 2 to represent rural background conditions. This would therefore indicate that the concentrations of 2,3,7,8-TCDD found in rural estuarine locations in NJ would result in reproductive failure in oysters. The presence of robust oyster beds in NJ estuarine waters demonstrates this is not the case.

EPA's use of inappropriate and indefensible ecological toxicity thresholds in the FFS is not limited to 2,3,7,8-TCDD or other organochlorine compounds. The toxicity thresholds applied in the FFS for metals are similarly flawed in their selection and application. For example, the FFS relies on CBR-based TRVs for copper in fish that are completely unsupportable, both from an EPA policy standpoint (see discussion below regarding the inappropriate use of a CBR approach for metals other than mercury and organo-selenium) and from an scientific standpoint.

The copper fish CBR TRV used in the FFS ERA is based on Zyadeh and Abdel-Baky (2000). This study examined the acute toxicity of copper to striped mullet (*Mugil cephalus*) from water-borne dissolved copper exposures. Juvenile mullet were exposed for 24 to 168 hours to four water concentrations of copper (0.5, 2, 5 and 10 mg/L). The LOAEL derived for the FFS was based on the results from the 24 hr 10 mg/L exposure which had a corresponding body residue concentration of 7.5 mg/kg ww. EPA applied a five-fold acute-to-chronic extrapolation factor because of the short exposure duration for determination of the LOAEL (1.5 mg/kg ww). The NOAEL was based on the 5 mg/L exposure, which corresponded to a tissue level of 1.6 mg/kg ww. EPA applied a five-fold extrapolation factor to yield the tissue NOAEL of 0.32 mg/kg ww for copper.

The exposure to copper in Zyadeh and Abdel-Baky (2000) was solely from water (i.e., not from exposure to sediment or food). As stated USEPA (2007b): "risk assessors are cautioned against extrapolating CBRs across differing exposure routes (food vs. water), durations, tissues, or species, because the potency of metal residues often differs depending on these factors." Therefore, the result of Zyadeh and Abdel-Baky (2000) do not in any way inform the FFS risk assessment regarding potential exposure to copper from sediment, which, according to Table 4-9 of the FFS, is the exposure pathway that EPA supposedly evaluated in the FFS. The FFS does not evaluate surface water exposures to copper. Rather the FFS specifically states that "risks from exposure to contaminated surface water will be evaluated in the 17-mile BERA". Furthermore, regarding the nature and extent of contamination in surface water, the FFS RI concludes that the evaluation of water column data was "hindered" by limited data, undefined datasets and data variability. Even so, the FFS RI states that, "...contaminants in the water column were primarily borne by the suspended solids as opposed to the dissolved phase." Nevertheless, the FFS wrongly relies on the copper fish CBR derived from Zyadeh and Abdel-Baky (2000), which is an assessment of toxicity from exposure to dissolved copper at concentrations up to 4,000 times EPA's copper AWQC, to make determinations about the purported risks to fish posed by copper in sediment. Furthermore, the use of a CBR approach for metals in the FFS is contrary to EPA's *Framework for Metals Risk Assessment* (USEPA, 2007), as discussed below in the overarching CBR/TRV issues.

Details on five overarching issues with the selected CBRs/TRVs are discussed below.

a) The disconnect between exposure and effects thresholds used to derive CBRs results in CBRs associated with very low confidence

Some of the CBRs are tissue concentrations based on interpolations with data obtained from multiple studies that used different study designs (i.e., different doses, exposure durations, and measurement endpoints). The modeled concentrations were also based on simplified or generic assumptions (i.e., linear dose- or concentration-response relationships). The justification for the assumptions used is inadequate and the interpolations are not reproducible, either due to lack of transparency or erroneous calculations. CBRs for which derivation methods lack transparency and reproducibility should not be used to determine baseline risks or provide the basis for cleanup levels.

b) The use of field studies to derive CBRs/TRVs where other contaminants and non-chemical stressors confound the ability to link exposure thresholds of single chemicals to effects and result in highly uncertain thresholds

CBRs and TRVs based on field studies or field-collected prey are highly uncertain and should only be used based on scrutinizing consideration of the study; the presence of multiple contaminants and other stressors in the field complicates the linkage between observed effects and exposure concentrations of single contaminants. As stated in USEPA (1998) regarding field studies, "*The presence of confounding factors can make it difficult to attribute observed effects to specific stressors. For this reason, field studies designed to minimize effects of potentially confounding factors are preferred, and the evidence for causality should be carefully evaluated…causality is the relationship between cause (one or more stressors) and effect (response to the stressor[s]). Without a sound basis for linking cause and effect, uncertainty in the conclusions of an ecological risk assessment is likely to be high*".

c) The evaluation of metals and PAHs using a CBR approach is not an appropriate measure for deriving risk estimates

The CBR approach for copper and lead for invertebrates and fish and for PAHs and fish is not appropriate. As stated in footnote e of Table 5-2 in the Region 2-approved PFD (Windward and AECOM 2009), for chemicals that are metabolized or otherwise regulated by fish, a tissue response approach is not appropriate. Tissue body burdens of most metals are biologically regulated, and because of the wide range of strategies used by aquatic organisms to store, detoxify, and excrete bioaccumulated metals, it is difficult to develop broadly applicable tissue residue toxicity thresholds for these organisms for metals (except mercury and selenium). Furthermore, metals uptake rates, which strongly influence whether bioavailable metals levels in tissue may be toxic, are influenced by site-specific factors (Adams et al. 2011). In addition, the use of the CBR approach for most metals is contrary to USEPA (2007b), which states: "For metals (aside from organo-selenium and methyl mercury), the situation is far more complex [than organic chemicals] and the CBR approach does not appear to be a robust indicator of toxic dose". USEPA (2007b) further states: "Although many toxicological studies report measurements of metal residues in multiple tissues along with adverse effects, these tissue residue values may not be appropriate for use as a CBR threshold because metal concentrations in some tissues may have little or no relationship with toxicity. Furthermore, risk assessors are cautioned against extrapolating CBRs across differing exposure routes (food vs. water), durations, tissues, or species, because the potency of metal residues often differs depending on these factors." The FFS ERA relies on TRVs for metals that were derived contrary to USEPA (2007b), extrapolating across different exposure routes (e.g., the derivation of the fish copper CBR based on aqueous dissolved copper exposure to estimate dietary and sediment exposure in the LPRSA).

d) The use of extrapolation factors without justification for their use to derive thresholds lower than reported in the literature is not appropriate for determining baseline risks and PRGs

The frequent use of extrapolation factors is unjustified and results in overly conservative and unsupported thresholds. Rationale for the application of extrapolation factors is unsatisfactory; use of "best professional judgment" in the selection of uncertainty factors is not well justified, which is contrary to EPA

guidance on risk assessment (Step 6 of the risk characterization process): "*Any extrapolations that are required to relate measurement to assessment endpoints (e.g., between species, between response levels, from laboratory to field) are explained*" (USEPA 1997). Furthermore, according to USEPA (1998): "*Despite their usefulness, uncertainty factors can also be misused, especially when used in an overly conservative fashion, as when chains of factors are multiplied together without sufficient justification. Like other approaches to bridging data gaps, uncertainty factors are often based on a combination of scientific analysis, scientific judgment, and policy judgment...it is important to differentiate these three elements when documenting the basis for the uncertainty factors used.*" Extrapolation factors are highly uncertain and are not recommended for the derivation of CBRs/TRVs, especially without a detailed uncertainty discussion of the CBRs/TRVs in question and the HQs derived from them.

e) Use of chicken reproductive toxicity studies to assess potential reproductive toxicity to birds in the LPR is not appropriate

TRVs based on domestic reproductive endpoints are not appropriate because domesticated species such as chickens (and quails) have altered egg-laying rates compared to wild bird species, and toxicological and reproductive sensitivities that are very different from those of wild bird species. Therefore, TRVs for birds should not based on egg productivity or other reproductive endpoints in a domesticated species, such as chickens or Japanese quail, particularly in a baseline risk assessment. Comparing toxic threshold effects on reproductive endpoints for these species using reproductive endpoints for non-domesticated species is problematic because of differences in reproductive physiology.

In addition, chickens are known to be highly sensitive to PCBs and dioxin-like compounds. Using the amino acid sequences of the ligand-binding domain of the aryl hydrocarbon receptor in individual bird species, birds have been grouped into three classifications of sensitivity to dioxin-like compounds: 1) high sensitivity, 2) moderate sensitivity, and 3) low sensitivity (Farmahin et al. 2013). Of the 86 bird species tested, chickens are in the high sensitivity group along with only 4 other species (red jungle fowl, European starling, ruby-throated hummingbird, and gray catbird). Therefore, toxicity data from studies with chickens used in the FFS are likely to overpredict PCDD/PCDF sensitivity for LPRSA species, such as the great blue heron (which is in the low sensitivity group).

3. <u>The assumptions used in the fish and bird egg modeling methods are based on generic assumptions rather than using site-specific and receptor-appropriate assumptions.</u>

The FFS ignored available site- and receptor-specific data for modeling egg concentrations, which affected the calculated egg risk estimates. In addition, the FFS failed to discuss the discrepancy between the bird egg tissue and bird diet HQs (an order of magnitude difference in HQs). The following generic assumptions were used in the egg modeling methods of the FFS:

- The FFS citation of regional cormorant egg tissue concentrations to justify the accuracy of modeled LPRSA egg tissue concentrations is invalid and erroneously cited. Cited concentrations are based on chick plasma (not egg) concentrations. Furthermore, the actual egg concentrations reported in Parsons (2003) do not support the assertion made by the FFS that modeled LPR bird egg concentrations are supported by site-specific data (see specific comments for details).
- The FFS ERA only evaluated bird egg concentrations based on "generic fish," which constitutes an ecologically inaccurate assumption regarding prey size for the selected avian receptor, the great blue heron (see above).
- The use of egg modeling assumptions from a bird receptor not selected under the Region 2-approved PFD (Windward and AECOM 2009) (i.e., herring gulls) is not appropriate or justified.
- The FFS ERA fails to use site-specific mummichog lipid data in modeling egg concentrations collected for the purposes for modeling site-specific fish egg concentrations under the Region 2-approved QAPP.

- The FFS cites using American eel data as part of a "generic fish" and as lipid data to model fish egg concentrations. The evaluation of fish eggs is relevant only for receptors expected to spawn in the lower 8.3 miles of the LPRSA. American eel do not reproduce in the LPRSA; they are believed to do so in the Atlantic Ocean, specifically in the Sargasso Sea (Brust 2006; NJDEP 2001). Therefore, the use of American eel data (as well as other fish included in the "generic fish") has no ecological basis.

4. The FFS fails to acknowledge the lack of habitat available in the lower 8.3 miles of the LPR for mink, which results in an inappropriate aquatic mammal receptor for the FFS ERA.

Evident of a lack of understanding of the urban nature of the LPR, the use of mink as a conservative surrogate for mammals in the FFS Study Area is not supported by site-specific data; there is no evidence that mink are present in the lower 8.3 miles of the LPRSA. Mink are not an appropriate aquatic mammal receptor for evaluation in the lower 8.3 miles of the LPRSA, and the calculated risks for mink for the entire lower 8.3 miles of the LPR (including HQs as high as 30 for PCDDs/PCDFs are misleading.

C. The FFS ecological CSM has not changed from the 2007 FFS despite the fact that more recent site-specific data have become available. The FFS ecological CSM is overly simplistic and inconsistent with the ecology of the LPR resulting in a poor understanding of exposure relationships and trophic transfer. The failure to better understand the LPR has resulted in faulty risk conclusions and a skewed value of the preferred remedial alternative relative to other alternatives which has led to an unnecessary remedy. Region 2 needs to assess the current site-specific information to understand the actual abiotic-biotic relationships in the river, which will lead to a better-informed remedy selection process.

The FFS ecological CSM developed for the lower 8.3 miles of the LPR fails to correctly identify the appropriate routes of exposure and adequately define trophic transfer relationships, resulting in an inaccurate presentation of the ecological system of the LPR. Figure G6 depicts the Region 2's inaccurate FFS ecological CSM resulting from the limited use of available site-specific data and reliance on data from aquatic systems other than the LPR.

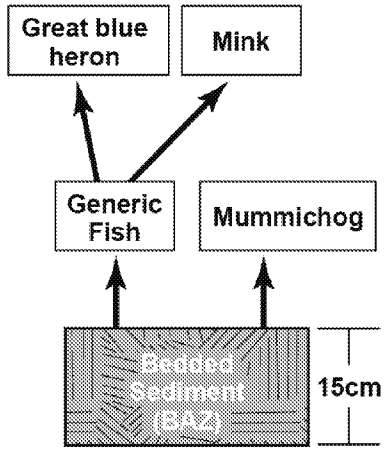
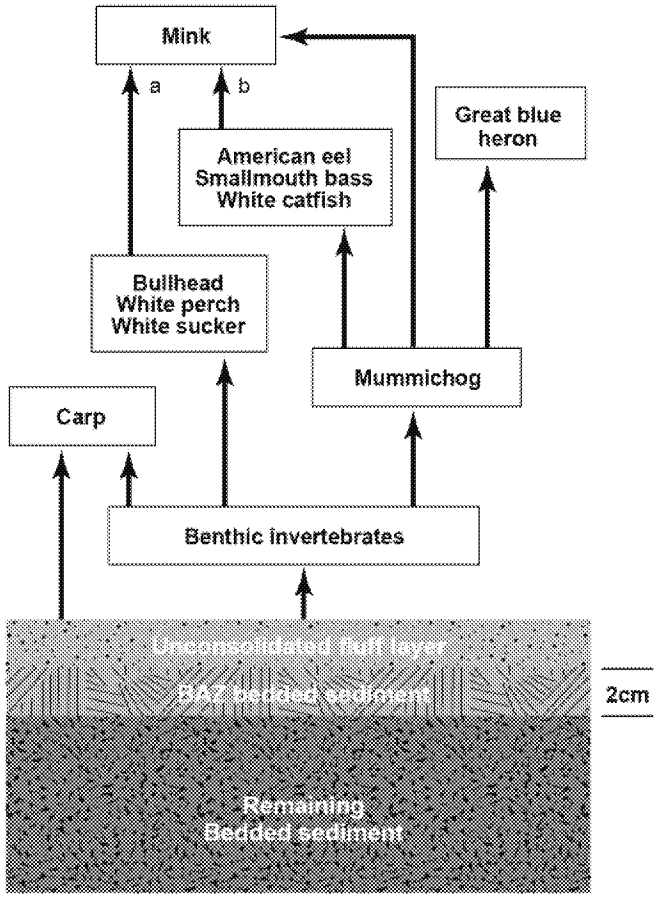


Figure G6. General FFS Ecological CSM for Identifying Principle Risk Drivers

Disregarding site-specific data, the FFS CSM creates a false relationship between bedded sediment chemical concentrations and fish tissue concentrations that is inaccurate and overly simplistic. The FFS ERA (Appendix D, Section 4.1.3, p. 4-13) states: "*The CSM is developed during the first step of the DQO process and continues to evolve throughout a project as historical and recently collected data are evaluated, DQOs are updated, and the risk assessments refined.*" The FFS failed to meet this standard.

The CPG, with Region 2's approval and oversight, collected significant data that was available in sufficient time to have been incorporated into the FFS (see the specific comment tables for the Region 2-approved QAPPs, which include 19 QAPPs for data collected since 2008). The use of these data would have resulted in a more accurate ecological CSM and provided Region 2 with a far clearer understanding of the ecological characteristics of the lower 8.3 miles of the LPR and risks related to specific sediment-trophic relationships.

In contrast to the FFS ecological CSM developed by Region 2, Figure G7 presents a site-specific CSM for the lower 8.3 miles of the LPR that incorporates all of the site-specific information and data that were available to Region 2 when the FFS was being developed.



[a] Bullhead and white perch based on site-specific size range of fish collected.
[b] Smallmouth bass based on site-specific size range of fish collected.

Figure G7. General Site-specific Ecological CSM for Identifying Principle Risk Driver

The critical differences between the two CSMs include the following:

1. <u>The depth of the biologically active zone (BAZ):</u>

Contrary to EPA guidelines, Region 2 relied on data from Newark Bay (Diaz 2008) to determine a BAZ for the LPR of 15 cm when site-specific data from the LPR was available. Site-specific observations and data developed by Germano & Associates (2005) for the LPR identifies almost all biological activity as

occurring in the aerobic zone, which is limited to the upper few centimeters of the sediment surface (mean of 1.9 cm); there is little evidence of biological activity extending below the aerobic zone (i.e., below the apparent redox potential discontinuity). Both studies (Germano & Associates 2005; Diaz 2008) employed the same equipment and applied similar analytical approaches to the resulting data. Region 2 is familiar with the work of and conclusions reported by Germano & Associates (2005), as the agency funded the work through the consultant group. The significance of the differences in the BAZ is important in understanding the exposure environment for the benthic community, which forms the basis for the majority of the food chain in the Passaic River. Germano & Associates (2005) noted the presence of benthic organisms was primarily limited to the sediment surface, or in the shallow sediment. Their presence in this shallow zone limits chemical exposure to the more recently deposited sediment and the layer of unconsolidated material (i.e., fluff layer) common in salt wedge estuaries. Chemical concentrations in this shallow layer are predicted to be lower than those in the top 15 cm because on the contributions of off-site material. In effect, Region 2's selection of the Newark Bay data (instead of a LPR-specific study) to estimate the BAZ leads to a faulty CSM that incorrectly includes chemical exposure to deeper bedded sediments that are not part of the exposure environment and do not impact fish tissue bioaccumulation.

2. The complexity of the fish community and its role in trophic transfer of hazardous substances is grossly simplified:

The Region 2 CSM for the LPR essentially assumes there are two types of fish that are relevant in trophic transfer and ecological interrelationships:1) mummichog and 2) all other fish. As discussed in General Comment No. 2, the FFS consolidated all fish species, other than mummichog, into a single "generic fish," regardless of size, feeding guild, or exposure area, to assess risks to fish and to fish-eating birds and mammals. Comingling the various species diminished the ability of the Region 2 risk assessors to properly identify risks associated with specific fish species or trophic relationships for species consuming fish. Specific issues related to reliance on tissue concentrations from a "generic fish" are discussed in more detail above.

3. Application of the fish tissue concentrations from an artificially created "generic" fish overstates risks to fish-eating birds and mammals:

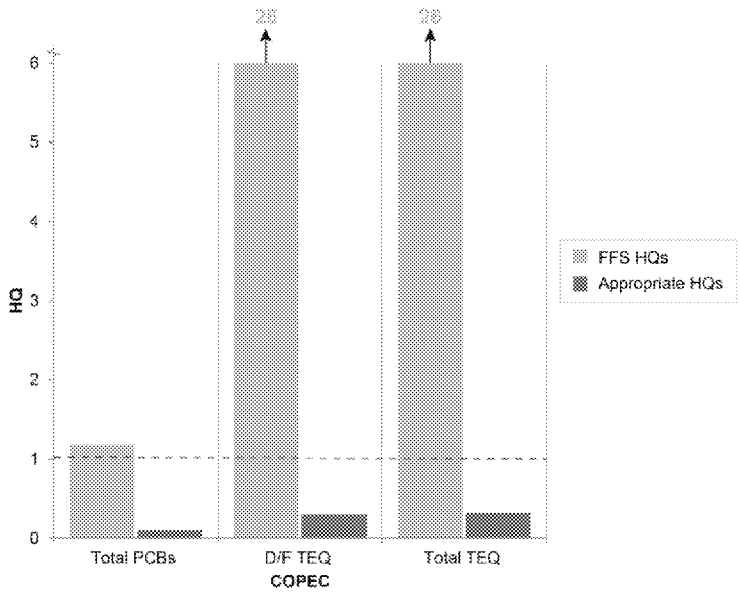
The FFS ERA uses the "generic fish" tissue concentration as a prey concentration in estimating risks to mammals and birds that consume fish. The use of the "generic fish" for this purpose is inappropriate for anything other than a screening-level assessment of risk posed to mammals and avian species utilizing the lower 8.3 miles of the LPR. As discussed in General Comment No. 2, fish-eating birds and mammals are limited in the size of fish they can prey upon, and most of the fish used to construct the "generic fish" exceed the size limit (Figures G3 and G4). The use of the "generic fish" as a prey source in estimating risks to fish-eating birds and mammals has a significant impact on perceived risks; resulting HQs are much lower when only appropriately sized fish are used as prey rather than "generic fish" (see Figures G10 and G11), reducing the inflated impression of high risks (i.e., based on high HQs derived from inappropriately sized fish) to birds and mammals from consuming prey from the LPR.

4. The inclusion of carp in the "generic fish" category is not justified:

Carp were not selected as an ecological receptor in the Region 2-approved PFD (Windward and AECOM 2009), and the protection of this invasive species is not warranted. Many studies have linked common carp to observable adverse impacts on aquatic habitats and the decreased suitability of those disturbed habitats for both aquatic and terrestrial wildlife. A number of jurisdictions have determined that carp are so detrimental to a functioning ecosystem that aggressive eradication programs have been introduced to control carp and their impacts on other species and habitat (Industry & Investment NSW 2010; Lougheed et al. 2004; Roberts and Tilzey 1997; Stuart and Jones 2002). The inclusion of carp in the "generic fish" category results in an overestimate of exposure concentrations and risks for fish species in the LPR identified for protection under the ERA. In addition, the inclusion of carp in the "generic fish" category also

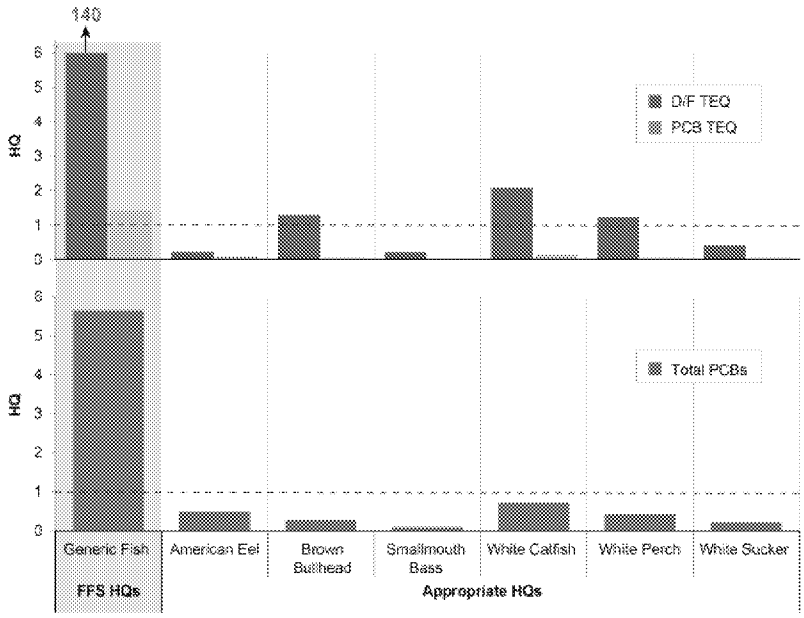
overestimates exposure concentrations and risks for fish-eating birds and mammals in the LPR because carp do not represent a reasonably-sized prey species.

In conclusion, the assessment of fish and wildlife risks that relies on screening-level type assumptions (i.e., generic exposure assumptions not supported by ecological or site-specific data and inappropriate and technically indefensible toxicity thresholds) has resulted in misleading hazard quotients (HQs) that overestimate risk to fish and wildlife. This has resulted in unrealistically low PRGs and the subsequent selection of an unnecessary remedy. Figures G8 through G11 present key examples of the differences between FFS ERA HQs based on generic assumptions and inappropriate toxicity thresholds and more appropriate HQs based on site-specific assumptions and appropriate toxicity thresholds. The risks presented in the FFS ERA are not representative of the lower 8 miles of the LPR and have led to a skewed quantification of the protectiveness of the preferred alternative relative to other alternatives.



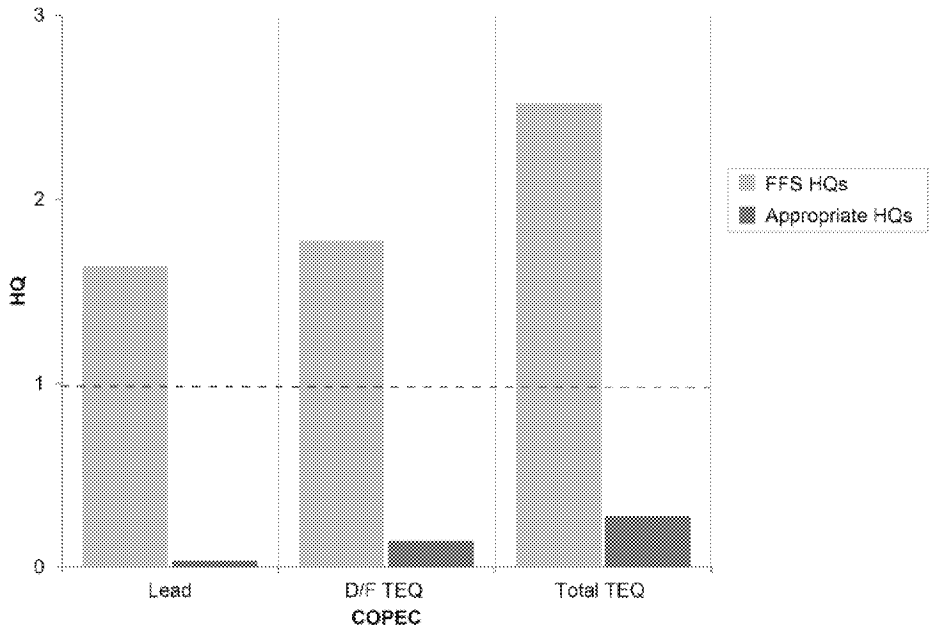
Note: Shown in Figure G8 are FFS HQs > 1 as reported in Table 4-15 of Appendix D. Appropriate HQs are based on FFS EPCs reported for mummichog (reported in Table 4-1 of Appendix D [Louis Berger et al. 2014]) and appropriate TRVs used in the LPRSA BERA (see Table 8). See Figure 5 in the specific comments for further detail.

Figure G8. Example LOAEL HQ Comparison for mummichog Tissue



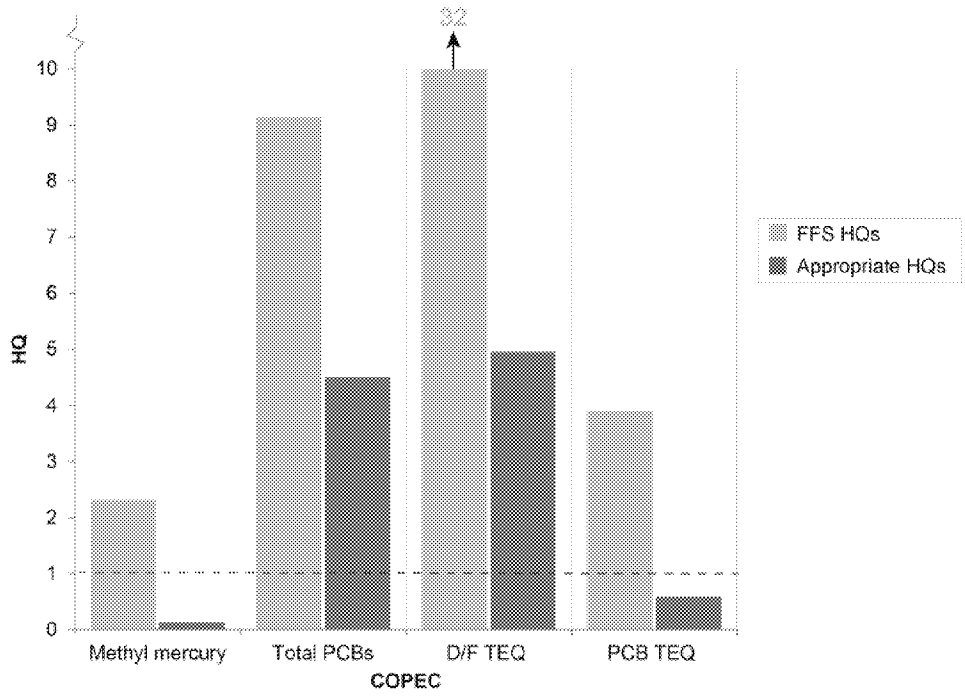
Note: Shown in Figure G9 are FFS HQs > 1 as reported in Table 4-15 of Appendix D. Appropriate HQs are based on CPG-calculated EPCs for individual fish species and revised TRVs used in the LPRSA BERA (see Table 8). See Figure 6 in the specific comments for further detail.

Figure G9. Example LOAEL HQ Comparison for* Generic *Fish and Other Fish Species



Note: Shown in Figure G10 are FFS HQs > 1 based on mummichog/crab diet as reported in Table 4-19 of Appendix D. Appropriate HQs are based on doses calculated from mummichog and blue crab EPCs as presented in FFS, a corrected SIR, sediment EPCs based on additional mudflat data not included in the FFS EPCs, and appropriate TRVs used in the LPRSA BERA. See Figure 9 in the specific comments for further detail.

Figure G10. Example LOAEL HQ Comparison for Resident Heron Diet



Note: Shown in Figure G11 are FFS HQs > 1 as reported in Table 4-19 of Appendix D. Appropriate HQs are based on doses calculated with fish EPCs based on appropriately sized fish tissue (i.e., fish < 30 cm), blue crab EPCs as presented in the FFS, a corrected SIR, sediment EPCs calculated with additional available sediment data that were not included in the FFS, and appropriate TRVs used in the LPRSA BERA. See Figure 10 in the specific comments for further detail

Figure G11. Example LOAEL HQ Comparison for Mink diet

The following presents the specific comments to the FFS ERA.

II. SPECIFIC COMMENTS TO APPENDIX D

A. Section 2 – Available data: The FFS ERA failed to use a comprehensive set of data collected for the purposes of risk characterization, and data reduction rules were not clearly documented and/or did not follow methods proposed for the LPRSA.

1. All available site-specific data critical for characterizing risk and defining site conditions were not used in the FFS ERA.

The CPG, under Region 2's approval and oversight, collected significant data which were available in sufficient time to have been incorporated into the FFS. Table 1 presents a comprehensive list of the Region 2-approved QAPPs that were approved for collection of data to support the risk assessment for the LPRSA. Shaded rows in Table 1 indicate which data were omitted from the FFS. The use of all of these data would have resulted in a more refined ecological CSM for the FFS and provided Region 2 with a far clearer understanding of the ecological characteristics of the lower 8.3 miles and risks related to specific sediment-trophic relationships.

Table 1. List of QAPPs and Data Reports (Shaded rows indicate data not incorporated into the FFS)

QAPPs			Associated Data Reports	
Document	**Date Approved by Region 2**	**Quantity of Data Collected**	**Document**	**Date Approved by Region 2**
Quality Assurance Project Plan: RI Low Resolution Coring/Sediment Sampling, Rev. 4 (ENSR/AECOM 2008)	October 20, 2008	55 locations in FFS Study Area	Revised Low Resolution Coring Report (AECOM 2014)	pending approval; submitted April 2014
Quality Assurance Project Plan: Fish and Decapod Crustacean Tissue Collection for Chemical Analysis and Fish Community Survey (Windward 2009a)	August 6, 2009	57 whole body[a] samples from ≤ RM 8	2009 Fish and Blue Crab Tissue Chemistry Data Report for the Lower Passaic River Study Area (Windward [in prep]-c)	pending approval; submitted September 19, 2011
Quality Assurance Project Plan: Fish and Decapod Crustacean Tissue Collection for Chemical Analysis and Fish Community Survey (Windward 2009a)	August 6, 2009	65 locations in FFS Study Area	Fish and Decapod Field Report for the Late Summer/Early Fall 2009 Field Effort (Windward 2010c)	September 14, 2010
Quality Assurance Project Plan: Surface Sediment Chemical Analyses and Benthic Invertebrate Toxicity and Bioaccumulation Testing (Windward 2009b)	October 8, 2009	50 locations in FFS Study Area	2009 and 2010 Sediment Chemistry Data for the Lower Passaic River Study Area (Windward [in prep]-a)	pending approval; submitted September 2, 2011
Quality Assurance Project Plan: Surface Sediment Chemical Analyses and Benthic Invertebrate Toxicity and Bioaccumulation Testing (Windward 2009b)	October 8, 2009	50 locations in FFS Study Area	Fall 2009 Benthic Invertebrate Community Survey and Benthic Field Data Collection Report for the Lower Passaic River Study Area (Windward 2014a)	January 6, 2014
Quality Assurance Project Plan: Surface Sediment Chemical Analyses and Benthic Invertebrate Toxicity and Bioaccumulation Testing (Windward 2009b)	October 8, 2009	50 locations in FFS Study Area	Fall 2009 Sediment Toxicity Test Data for the Lower Passaic River Study Area (Windward [in prep]-k)	pending approval; submitted January 31, 2012
Quality Assurance Project Plan: Surface Sediment Chemical Analyses and Benthic Invertebrate Toxicity and Bioaccumulation Testing (Windward 2009b)	October 8, 2009	8 samples in FFS Study Area	2009 Bioaccumulation Tissue Chemistry Data for the Lower Passaic River Study Area (Windward [in prep]-b)	pending approval; submitted September 19, 2011

Table 1. List of QAPPs and Data Reports (Shaded rows indicate data not incorporated into the FFS)

QAPPs		Quantity of Data Collected	Associated Data Reports	
Document	Date Approved by Region 2		Document	Date Approved by Region 2
Winter 2010 Fish Community Survey, Addendum to the Quality Assurance Project Plan: Fish and Decapod Crustacean Tissue Collection for Chemical Analysis and Fish Community Survey, Addendum No. 1 (Windward 2010h)	January 25, 2010	36 locations in FFS Study Area	Fish Community Survey and Tissue Collection Data Report for the Lower Passaic River Study Area 2010 Field Efforts (Windward 2011c)	July 20, 2011
Late Spring/Early Summer 2010 Fish Community Survey, Addendum to the Quality Assurance Project Plan: Fish and Decapod Crustacean Tissue Collection for Chemical Analysis and Fish Community Survey, Addendum No. 3 (Windward 2010e)	June 22, 2010	86 locations in FFS Study Area		
Spring and Summer 2010 Benthic Invertebrate Community Surveys, Addendum to the Quality Assurance Project Plan: Surface Sediment Chemical Analyses and Benthic Invertebrate Toxicity and Bioaccumulation Testing, Addendum No. 1 (Windward 2010g)	May 17, 2010	16 locations in FFS Study Area	Spring and Summer 2010 Benthic Invertebrate Community Survey Data for the Lower Passaic River Study Area (Windward 2014d)	January 15, 2014
Late Spring/Early Summer 2010 Fish Tissue Collection, Addendum to the Quality Assurance Project Plan: Fish and Decapod Crustacean Tissue Collection for Chemical Analysis and Fish Community Survey, Addendum 4 (Windward 2010f)	June 21, 2010	18 whole body samples from ≤ RM 8	2010 Small Forage Fish Tissue Chemistry Data for the Lower Passaic River Study Area (Windward [in prep]-d)	pending approval; submitted July 18, 2012

Table 1. List of QAPPs and Data Reports (Shaded rows indicate data not incorporated into the FFS)

QAPPs		Quantity of Data Collected	Associated Data Reports	
Document	**Date Approved by Region 2**		**Document**	**Date Approved by Region 2**
Avian Community Survey, Addendum to the Quality Assurance Project Plan: Fish and Decapod Crustacean Tissue Collection for Chemical Analysis and Fish Community Survey, Addendum No. 2 (Windward 2010a)	August 9, 2010	12 locations surveyed in summer and fall in FFS Study Area	Avian Community Survey Data Report for the Lower Passaic River Study Area Summer and Fall 2010 (Windward 2011a)	August 8, 2011
		12 locations surveyed in winter and spring in FFS Study Area	Avian Community Survey Data Report for the Lower Passaic River Study Area Winter and Spring 2011 (Windward [in prep]-i)	pending approval; submitted July 17, 2012
Collection of Surface Sediment Samples Co-Located with Small Forage Fish Tissue Samples, Addendum to the Quality Assurance Project Plan: Surface Sediment Chemical Analyses and Benthic Invertebrate Toxicity and Bioaccumulation Testing, Addendum No. 2 (Windward 2010b)	August 13, 2010	16 locations in FFS Study Area	2009 and 2010 Sediment Chemistry Data for the Lower Passaic River Study Area (Windward [in prep]-a)	pending approval; submitted September 2, 2011
Habitat Identification Survey, Addendum to the Quality Assurance Project Plan: Surface Sediment Chemical Analyses and Benthic Invertebrate Toxicity and Bioaccumulation Testing, Addendum No. 3 (Windward 2010d)	September 13, 2010	67 locations surveyed in FFS Study Area	Habitat Identification Survey Data Report for the Lower Passaic River Study Area Fall 2010 Field Effort (Windward 2014b)	January 6, 2014
Caged Bivalve Study, Addendum to the Quality Assurance Project Plan: Surface Sediment Chemical Analyses and Benthic Invertebrate Toxicity and Bioaccumulation Testing, Addendum No. 4 (Windward 2011b)	March 2, 2011	3 soft tissue samples in FFS Study Area	2011 Caged Bivalve Study Data for the Lower Passaic River Study Area (Windward [in prep]-e)	pending approval; submitted July 18, 2012
Quality Assurance Project Plan, Lower Passaic River Restoration Project, Low Resolution Coring Supplemental Sampling Program, Rev. 3 (AECOM 2012)	June 2012	66 locations in FFS Study Area	Low Resolution Coring Supplemental Sampling Program Characterization Summary (AECOM 2013)	pending approval; submitted August 2013

Table 1. List of QAPPs and Data Reports (Shaded rows indicate data not incorporated into the FFS)

QAPPs			Associated Data Reports	
Document	Date Approved by Region 2	Quantity of Data Collected	Document	Date Approved by Region 2
Quality Assurance Project Plan/Field Sampling Plan Addendum, RI Water Column Monitoring/Small Volume Chemical Data Collection, Rev. 2 (AECOM 2011)	2011	4 locations sampled in FFS Study Area at 5 sampling events between 8/2011 and 8/2012	Small Volume Chemical Water Column Monitoring Sampling Program Characterization Summary (AECOM [in prep])	pending approval; submitted February 2014
Summer and Fall 2012 Dissolved Oxygen Monitoring Program, Addendum to the Quality Assurance Project Plan: Remedial Investigation Water Column Monitoring/Physical Data Collection for the Lower Passaic River, Newark Bay, and Wet Weather Monitoring, Addendum No. 1 (Windward 2012c)	August 6, 2012	5 locations sampled in FFS Study Area	Dissolved Oxygen Monitoring Program Data Report for the Lower Passaic River Study Area: Summer and Fall 2012 (Windward [in prep]-j)	pending approval; submitted September 3, 2013
Background Tissue Addendum to the Quality Assurance Project Plan: Fish and Decapod Crustacean Tissue Collection for Chemical Analysis and Fish Community Survey, Addendum No. 5 (Windward 2012b)	October 10, 2012	56 whole body[a] samples above Dundee Dam	document in preparation	document in preparation
Background and Reference Conditions Addendum to the Quality Assurance Project Plan: Surface Sediment Chemical Analyses and Benthic Invertebrate Toxicity and Bioaccumulation Testing, Addendum No. 5 (Windward 2012a)	October 26, 2012	24 locations sampled Dundee Dam	2012 Benthic Invertebrate Community Reference Data for the Lower Passaic River Study Area (Windward [in prep]-f)	pending approval; submitted August 26, 2013
		24 locations sampled Dundee Dam	2012 Sediment Toxicity Reference Data for the Lower Passaic River Study Area (Windward [in prep]-h)	pending approval; submitted October 22, 2013
		40 locations sampled Dundee Dam	2012 Sediment Chemistry Background Data for the Lower Passaic River Study Area (Windward [in prep]-g)	pending approval; submitted October 30, 2013

[a] Count based on whole body samples and reconstituted whole body samples analyzed.

These data were all made available to Region 2, and most data were collected between 2010 and 2012 which provided sufficient time for its inclusion in the 2014 FFS ERA. Since the 2007 FFS was produced, other than the inclusion of the recent fish tissue data, no attempt has been made to incorporate other relevant data sources into the 2014 FFS, and the 2014 FFS provides no justification as to why these sources were omitted.

2. The data rules established in the *Data Usability and Data Evaluation Plan for the LPRSA* (Windward and AECOM 2014) were not followed for the FFS risk assessments.

The *Data Usability and Data Evaluation Plan for the LPRSA* (Windward and AECOM 2014), which underwent multiple rounds of review by Region 2, includes the criteria for establishing an acceptable data set for calculating exposure estimates for LPRSA risk assessments and defines data rules and data quality objectives (DQOs). The FFS data rules were inconsistent with the proposed data rules in the following cases:

Section 2.2: Data compilation for the BERA. Per the data DQOs outlined in the *Data Usability and Data Evaluation Plan for the LPRSA* (Windward and AECOM 2014), no sediment locations that have been dredged or capped should be included for use in the risk assessments. Sediment chemistry in samples that have been dredged no longer represent current conditions. Contrary to The Data Usability and Data Evaluation Plan for the LPRSA following dredged locations at Lister Ave were included in the risk assessment data set: LPRT03F and LPRT03G.

Section 2.4. Data standardization and summary procedures. Sum components for the LPRSA risk assessments were defined in the *Data Usability and Data Evaluation Plan for the LPRSA* (Windward and AECOM 2014). The FFS use summing procedures contrary to the proposed rules in the following cases:

- Total PCBs excludes 12 dioxin-like PCBs. There is no precedent for summing PCBs in this manner.
- Components of total LPAHs, HPAHs, and DDx were not consistent with *The Data Usability and Data Evaluation Plan for the LPRSA* as presented in Windward and AECOM (2014).

Section 2.3. Data usability evaluation and Attachment 1.4. The *Data Usability and Data Evaluation Plan for the LPRSA* (Windward and AECOM 2014) states that parent and field replicate samples should be averaged for use in the risk assessment data set; the FFS did not evaluate field replicate samples.

3. Data documentation or justification was insufficient to understand the specific data used in risk calculations.

Examples of documentation deficiencies are as follows:

Section 2.1 and 2.2: Data compilation for the HHRA and BERA. The FFS Study Area is defined as RM 0 to RM 8.3 in the main text of the FFS; however, data from RM 0 to RM 8 are used in the risk assessments (there are additional sediment sampling locations between RM 8 and 8.3)

Section 2.4. Data standardization and summary procedures. Components of total LPAHs and HPAHs are not clearly provided in Appendix D. A footnote describing sum constituents was identified in Table 3-1 of Data Evaluation Report No. 4: "Surface Sediment Contamination"; however, EPCs could not be replicated based on these sum definitions.

Section 2.2: Data compilation for the BERA, p. 2-3, 1st paragraph. The basis and justification of "mudflat samples" is unclear. As stated, the mudflat area: "consisted of 17 sediment samples collected between 2009 and 2011 included in the BERA data set that were identified as mudflat samples based on their location in the shoal areas of the Passaic River that could potentially be exposed during low tide."

However, the basis for this mudflat definition is unclear and does not appear to take into account depth and slope.

Section 2.3.1: Method detection limits, p. 2-8 and Attachment 3 of Appendix D. The FFS cites use of ProUCL for calculating EPCs based on UCLs. UCLs could not be replicated in some cases based on the data provided in Appendix D:

- ProUCL is designed to account for non-detects in a data set. Based on the ProUCL output presented in Attachment 3, it appears that program options were defined improperly when running UCLs, such that the program processed data sets as though no non-detects were present even when this was not the case.
- ProUCL output (e.g., n, min, max) indicate discrepancies between EPC data sets and the sample lists provided in Attachment 1.1. For example, Attachment 1.1 identifies 17 mudflat samples for copper, but ProUCL output indicates 21 samples.
- ProUCL output indicates discrepancies between recommended UCL values and those used in the risk assessment. For example, copper UCLs for mudflats (UCL = 240 mg/kg) and RM 0-8.3 (UCL = 160 mg/kg) are different from those reported in Table 4-1 (220 and 170 mg/kg, respectively).
- Not all ProUCL output is included in Attachment 1.1 (e.g., 2,3,7,8-TCDD).

B. Section 4: Baseline ecological risk assessment – baseline conditions: The FFS ERA failed to incorporate all appropriate site-specific data, and used generic and inappropriate exposure and effects thresholds that resulted in an overestimation of ecological risks.

1. In the COPEC screening process, tissue data were not used (only sediment data and invertebrate sediment thresholds and back-calculated fish and wildlife sediment thresholds were evaluated), despite the fact that tissue data were the basis for the fish and wildlife risk assessment.

Section 4.1.1: Identification of contaminants of potential ecological concern. Inclusion of tissue data in the screen for contaminants of potential concern (COPC) may result in different COPCs for the risk assessment for fish and wildlife. The proposed COPEC screening process was outlined in Appendix A of the *Risk Analysis and Risk Characterization Plan for the Lower Passaic River Study Area* (Windward and AECOM [in prep]).

2. The benthic community risk assessment conducted in the FFS is equivalent to a screening level risk assessment that ignores available co-located site-specific sediment toxicity, benthic community, and sediment chemistry data. This has resulted in the FFS's gross overstatement of risks to the benthic community and an unnecessarily low PRG and subsequent selection of bank-to-bank remedy. Conducting an ERA without using the available site-specific data for a sediment quality triad (SQT) analysis and including a comparison to reference information has resulted in the FFS's gross overstatement of risks to the benthic community.

Section 4.1.3: Conceptual site model, p. 4-14, last paragraph. Evaluation of risk to infaunal benthic invertebrates. The FFS states the invertebrates that live in the sediment were evaluated through sediment chemistry data. However, the sediment quality triad (SQT) approach, which incorporates three lines of evidence collected concurrently (i.e., benthic community structure, toxicity test, and sediment chemistry data), was not used for the FFS ERA. The data for all three lines of evidence collected in 2009 were available to Region 2 and the SQT approach is presented in the Region 2-approved PFD (Windward and AECOM 2009) and the Region 2-approved Benthic QAPP (Windward 2009b) for the 17.4-mile RI/FS. It is inconsistent and overly conservative to use only sediment chemistry to assess risk to infaunal benthic invertebrates for the 8.3 river mile portion of the LPRSA included in the FFS study area.

Region 2 has based the assessment of risk to infaunal benthic invertebrates on comparison to sediment benchmarks (the LRM-based low and high criteria [i.e., T20 and T50] and ER-Ls and ER-Ms) to evaluate baseline risks to infaunal benthic invertebrates in the LPRSA (from RM 0 to RM 8.3). As noted in the following documents, SQGs are intended for screening purposes and should be used in conjunction with additional site-specific data:

- USEPA (2005b) states that LRMs should not be considered a complete substitute for direct-effects assessment (e.g., toxicity tests).
- NJDEP (2012) states that ecological evaluation of sediment contamination should consider background concentrations relevant to urban conditions. The comparison of sediment chemistry data to NJDEP ecological screening criteria, which are not promulgated standards, is intended as a screening-level evaluation, preliminary to further comparison to background.
- NJDEP (2012) requires that the evaluation of sediment quality follow the SQT paradigm, in that sediment chemistry, sediment toxicity, and benthic community data be evaluated in a weight of evidence approach; in the BERA for the FFS, Region 2 implemented only the first line of evidence, sediment chemistry data as it relates to established ecological screening criteria or the LRM, depending on the chemical.
- Long et al. (1998) states that ERMs are not intended to represent effects thresholds above which adverse effects would always be observed. SQGs can be used in ecological risk assessments at these sites to estimate the potential for adverse biological damage. Ecological risk assessments of sediments are most comprehensive when all three components of the sediment quality triad are included in the approach. SQGs should be used in conjunction with other tools within an integrated framework for assessing sediment quality.
- Long et al. (2006) states that SQGs should be included with other measures including results of toxicity tests and benthic community surveys to provide a weight of evidence when assessing the relative quality of contaminated sediments.
- NOAA (1999) states that SQGs were developed as informal, interpretive tools for the National Status and Trends Program to rank areas that warranted further detailed study on the actual occurrence of adverse effects such as toxicity. The guidelines were not promulgated as regulatory criteria or standards but were intended as informal (non-regulatory) guidelines for use in interpreting chemical data from analyses of sediments. Toxicity must be confirmed with empirical data from toxicity tests.
- Ingersoll et al. (2005) summarize the large number of published studies that have evaluated the ability of SQGs to predict effects observed in laboratory toxicity tests or in field studies of benthic communities. The LRM is included in the evaluation. The ultimate conclusion is that whenever possible, decisions regarding the management of contaminated sediments should be made using a WOE approach. Ingersoll et al feels that it is appropriate, based on their review of the numerous studies, that sediment management decisions can be made using sediment chemistry data only (i.e., with SQGs) at sites where the costs of further sediment assessments are likely to approach or exceed the costs of sediment remediation. Since toxicity test data and benthic community data were collected concurrently with some of the chemistry data, SQT assessment should be conducted as presented in the Region 2-approved PFD and a WOE approach used to make remediation decision in the LPRSA.
- Sediment criteria values such as the ER-L/ER-M and the LRM have been stated by several authors (O'Connor 2004; O'Connor et al. 1998; Wetherington et al. 2005) to be useful for screening purposes, but inappropriate or inaccurate for characterizing risk as was done in the BERA for the FFS. Specifically, Wetherington et al. (2005) showed that the LRM resulted in a false positive rate of 55% when applied to EPA's National Sediment Inventory database. O'Connor (2004) notes that ER-L values, which are not predictive of toxicity, are inappropriate for use in the characterization of risk. O'Connor et al. (1998) noted that, although the ER-L was accurate for predicting no toxicity, the ER-M only accurately predicted toxicity in 38% of sediment samples (n= 1,508); O'Connor et al. (1998) suggest that the ER-M be used to identify samples for

further examination, in that biological data (e.g., toxicity and benthic community data) be evaluated at the same time as co-occurring sediment chemistry (Adams et al. 1992).

- Chapman (2002) states that there is general agreement in the scientific community that toxicity cannot be defined solely on the basis of chemistry. Toxicity as an ecological response is best measured directly.
- Guidance from the NYSDEC (2013) says that SQVs are primarily useful as the initial step in the evaluation of sediment contamination. NYDEC considers SQVs a conservative tool for making an initial assessment of the potential risks that might be associated with contaminants in a sediment sample.
- USEPA (1998) states that, "Field surveys usually represent exposures and effects (including secondary effects) better than estimates generated from laboratory studies or theoretical models. Field data are more important for assessments of multiple stressors or where site-specific factors significantly influence exposure. They are also often useful for analyses of larger geographic scales and higher levels of biological organization." The BERA conducted by Region 2 for the FFS did not take into account site-specific field survey data collected to support the sediment chemistry data. Benthic community survey data were available to Region 2 (Windward 2014a).
- USEPA (1999) provides clear guidance for risk managers on the use of field data by stating, "the baseline risk assessment may include site-specific toxicity tests with test organisms that address the endpoints selected for the site. Through the use of field studies and/or toxicity tests, several types of data may be developed to provide supporting information for a lines-of-evidence approach to characterizing site risks. **This approach is far superior to using single studies or tests or measurements to determine whether or not the observed or predicted risk is unacceptable."** In the FFS, Region 2 has applied single studies or measurements (i.e., sediment chemistry line of evidence) in order to characterize risk, which, as cited, is an inferior approach to characterizing risk according to USEPA (1999).
- USEPA (2005b) states that, "Before applying the [LRM] models to a particular site, we recommend first evaluating how well the models fit the local situation by collecting a test set of matching sediment chemistry and toxicity test data. The LRMs can be used to design effective test sampling programs, and they can also suggest issues that require further investigation (e.g., bioavailability). **The LRMs should not be considered a complete substitute for direct-effects assessment (e.g., toxicity tests)".** Region 2 has been supplied with toxicity test data from the LPRSA (Windward [in prep]-k) and could have incorporated such data into the evaluation of benthic invertebrate risk in the FFS as a second line of evidence.

3. The use of "generic" fish by combining data from multiple fish species (i.e., American eel, brown bullhead, common carp, smallmouth bass, white catfish, white perch, and white sucker) covering multiple feeding trophic levels, exposure histories, and sizes is not appropriate or ecologically accurate for characterizing risks to fish.

Section 4.1.3: Conceptual site model, p. 4-15, 1st paragraph. Contaminant levels are expected to vary among species with different feeding habits; thus, three general feeding guilds were selected for evaluation of potential risks to fish in the PFD (Windward and AECOM 2009): benthic omnivores, invertivores, and piscivores. The FFS "generic" fish is constructed from 7 fish species from these three feeding guilds, each of which represents a different exposure history based on feeding strategy resulting in varying tissue concentrations. In the bioaccumulation model, which is used to evaluate concentrations in tissue based on future sediment concentrations based on remedial alternatives, fish within different feeding guilds are modeled separately to account for these differences in contaminant concentrations across trophic levels.

4. The inclusion of carp in the "generic" fish category as an ecological species to be protected through the baseline ecological risk assessment is not appropriate and results in an

overestimate of exposure concentrations and risks for fish species in the LPR identified for protection under the ERA.

Section 4.1.3: Conceptual site model, p. 4-15. Carp were not selected as an ecological receptor in the Region 2-approved PFD (Windward and AECOM 2009) and the protection of this invasive species in not warranted. Many studies have linked common carp to observable adverse impacts on aquatic habitats and the decreased suitability of those disturbed habitats for both aquatic and terrestrial wildlife. The LPRSA is known to be degraded by multiple stressors common to urban streams (e.g., impaired water quality, organic and inorganic nutrient enrichment, presence of invasive species), and it is thought that common carp may actively contribute to the impairment of water quality and the alteration of the benthic invertebrate community in the LPRSA. These effects are attributed to the carp's method of feeding, which aggressively disturb surface sediment and increases turbidity. This behavior results in reduced biomass and diversity of submerged vegetation and can lead to shifts in the autotrophic community away from submerged aquatic vegetation and filamentous algae toward suspended algae (Chumchal et al. 2005; Weber and Brown 2011; Wahl et al. 2011). Impacts on benthic invertebrates due to carp activity can result in a community-level shift from benthic invertebrate species that utilize submerged aquatic vegetation for food or refuge (i.e., detritivore or omnivore species, such as gastropods and crustaceans) to those that consume organic carbon directly from sediment and/or burrow into sediment (i.e., tube-dwelling chironomids and deposit feeders, such as annelids) (Miller and Crowl 2006).

Consistent re-suspension of sediment and egestion can result in an increase in available phosphorus and nitrogen (Chumchal et al. 2005), which can foster rapidly growing unicellular algae (Chumchal et al. 2005; Weber and Brown 2011) that can further diminish light penetration, thereby creating a positive feedback loop that disfavors submerged vegetation. As a result, the benthic community can shift from species that utilize submerged vegetation for food or refuge (e.g., amphipods and decapods) (Carey and Wahl 2010; Hinojosa-Garro and Zambrano 2004; Parkos et al. 2003; Wahl et al. 2011) toward species that consume organic carbon directly from sediment (i.e., oligochaetes and chironomids). A number of jurisdictions have determined that carp are so detrimental to a functioning ecosystem that aggressive eradication programs have been introduced to control carp and their impacts on other species and habitat (Industry & Investment NSW 2010; Lougheed et al. 2004; Roberts and Tilzey 1997; Stuart and Jones 2002).

5. The use of "generic" fish by combining data from multiple fish species covering multiple feeding sizes is not appropriate or ecologically accurate for characterizing risks to fish-eating birds and mammals.

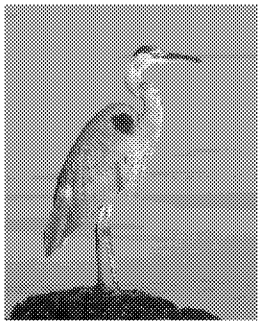
Section 4.1.3: Conceptual site model, p. 4-15. Combining fish across sizes is also not reasonable for estimating prey exposures for fish-eating bird and mammal receptors, who have limitations on the sizes of fish they can prey on. Large fish, such as carp, are not a realistic food source for birds and mammals and use of "generic" fish to derive HQs results in unrealistically high exposure concentrations.

Heron – The size of fish that heron will eat is limited by their beak size. Based on an average great blue heron beak length of 13.5 cm (Poole 2011), Krebs (1974) determined that over 92% of great blue heron fish prey are small or medium sized (up to about 6.8 cm), and the remaining fish prey are greater than or equal to the length of the beak (13.5 cm). Thus, the diet of the great blue heron should be limited to fish no larger than 13 cm long.

Only a fraction of the individual white perch analyzed from the lower 8.3 miles of the LPR are of suitable size for consumption (13 cm), but no perch composite samples include only fish ≤ 13 cm, and all other fish included in the "generic" fish category are larger than the suitable size (Table 2, Figure 1). In fact, the only species that meets the prey size requirements for the great blue heron (i.e., where all fish in each composite are less than 13 cm) is the mummichog. Therefore, only the mummichog data are appropriately sized fish prey for heron, therefore, only mummichog EPCs (not generic fish EPCs) should be used in the risk calculations for heron for both dietary and egg calculations.

Table 2. Summary of Fish Lengths in Analytical Samples Collected from the FFS Study Area

Species	No. of Samples	Length of Fish in Sample (cm)	
		Maximum	Mean
Benthic omnivore			
Mummichog	15	10	6.2
Carp	4	60.7	57.6
Invertivore/omnivore			
Brown bullhead	2	29.7	28.9
White perch	12	32.1	18.8
White sucker	1	32.7	32.7
Piscivore/invertivore			
American eel	10	63.5	52.7
Smallmouth bass	1	29.4	26.4
White catfish	6	47.1	40.7



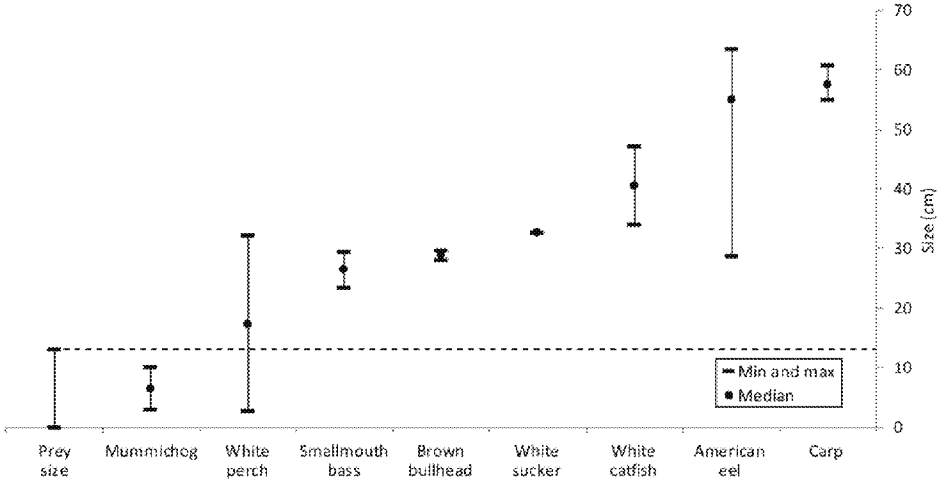


Figure 1. Heron Prey Size Compared to Samples Collected from the FFS Study Area

Mink – Mink are opportunistic feeders that generally prefer fish that are ≤ 30 cm in length. The results of an analysis of scat from mink in Idaho showed that the mink diet consisted of fish ranging in length from 7 to 30 cm; neither largescale sucker nor northern squawfish, which ranged from 35 to 45 cm, were consumed (Melquist et al. 1981). Another study in Great Britain (Britton et al. 2006) found that most fish consumed by mink were < 30 cm long, although some of the northern pike consumed were up to 70 cm. However, northern pike were only 1.5% of the mink's diet, so the overall percentage of large fish consumed was small. Thus, the diet of the mink should be limited to fish no larger than 30 cm long.

Only a limited portion of the size range of a single fish species included in the "generic" fish are based on individual fish that are within the suitable size range for consumption (30 cm) (Table 2, Figure 2). Only the following fish species from the "generic" fish category meet the prey size requirement for mink (i.e., where

all fish in each composite are less than the appropriate prey size): brown bullhead, smallmouth bass, and white perch. Mummichog should have also been included fish portion of the mink diet, as they represent an appropriately-sized fish prey as well that are abundant in the LPR, but were not included in the FFS mink diet. EPCs based on appropriately-sized prey for mink are presented in Table 3.

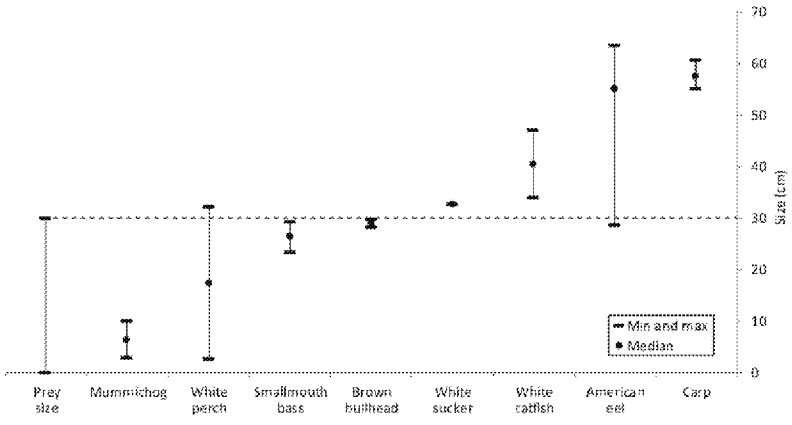


Figure 2. Mink Prey Size Compared to Samples Collected from the FFS Study Area

Table 3. Comparison of EPCs

Chemical	EPC (UCL) (mg/kg)	
	FFS Generic Fish[a]	All fish <30 cm[b]
Copper	12	7.9
Lead	0.50	1
Mercury	0.24	0.11
Methyl mercury	0.23	0.10
Total PCB Congeners	3.0	1.7
PCB TEQ-Mammal	0.033	0.019
2,3,7,8-TCDD	0.24	0.15
Dioxin TEQ-Mammal	0.25	0.15
Dieldrin	0.38	0.22
Total DDx	0.32[c]	0.19[d]

Note – PAH sums not included for comparison because it was unclear on what components were included in these sums.

[a] From Table 4-1 of Appendix D of the FFS (Louis Berger et al. 2014) .

[b] Includes mummichog, white perch < 30 cm, brown bullhead, and smallmouth bass.

[c] DDx appears to include only the three 4,4' isomers

[d] DDx includes all six isomers

Figure 3 shows a comparison of UCLs based on "generic fish" to UCLs based on appropriately-sized fish and illustrate how the 'generic fish" UCL overstates exposure and risks to birds and mammals, especially for key bioaccumulative chemicals.

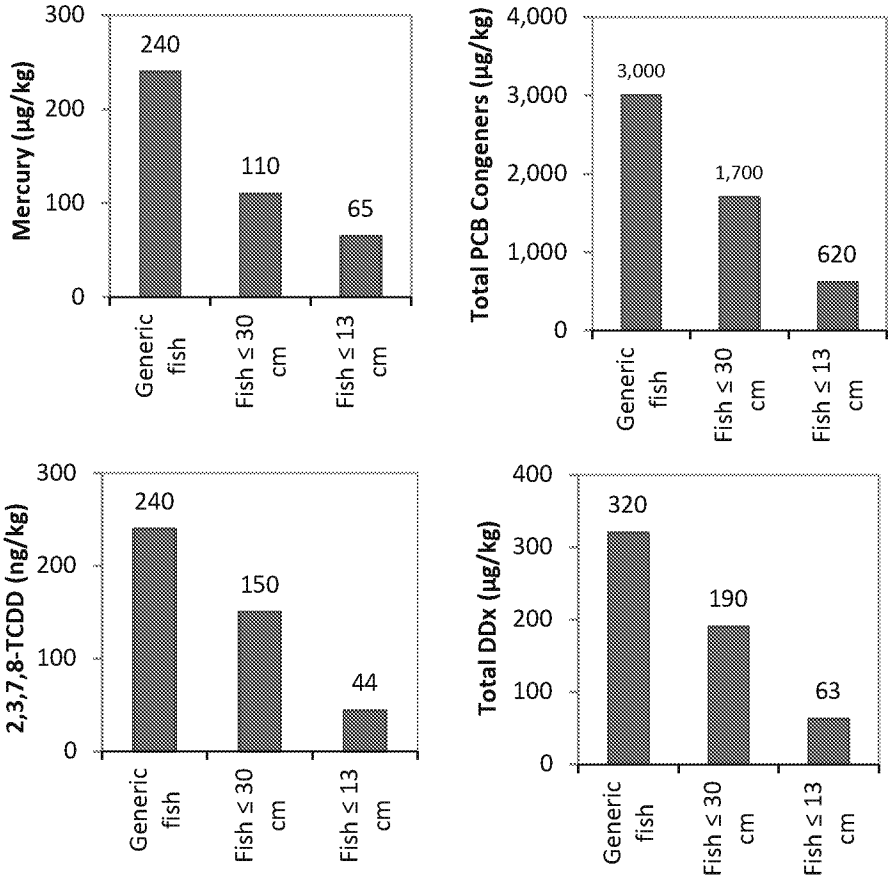


Figure 3. Comparison of UCLs of the FFS "Generic" Fish to Those Based on Size-Appropriate Prey for Heron (Fish ≤13 cm) and River Otter (Fish ≤30 cm)

6. The FFS fails to acknowledge the lack of habitat available in the lower 8.3 miles of the LPR for mink, which results in an inappropriate aquatic mammal receptor for the FFS ERA.

Section 4.1.3: Conceptual site model, p. 4-15, 2nd paragraph. The FFS states that mink were included as a receptor in the FFS because it "is a possible resident species". There is no evidence that mink are present in the lower 8.3 miles of the LPRSA. Mink are not an appropriate aquatic mammal receptor for evaluation in the lower 8.3 miles of the LPRSA.

Mink are rare in the LPRSA, likely as a result of poor habitat quality. There is no evidence of mink presence in or near the FFS Study Area. The only known evidence of potential mink activity in the LPR is based on the observation of mink tracks along the bank near Dundee Dam (at RM 17.4) in August 2010, (Windward 2011a); no other observations of mink in or near the LPRSA have been reported. Mink are generally limited to natural shorelines with access to water (Allen 1986) and are associated with dense wooded vegetation along streams and wetlands. In general, mink tend to avoid areas near human activity or limited vegetation, including areas of residential/recreational land use (Allen 1986; USEPA 2002a). Mink habitat preference is also highly influenced by prey accessibility (Burgess 1978). The land surrounding the LPRSA is mostly urban and industrial, with little dense wooded vegetation. The upper portion of the LPRSA (above approximately RM 10) has some vegetation, and is less

disturbed/developed than the lower portions of the LPRSA; however, this area does not represent optimal mink habitat. Suboptimal habitats are primarily used by dispersing mink (USFWS 2011; Linn as cited in Allen 1986) and are unlikely to support reproducing female mink or their offspring.

Anecdotal evidence from areas near the LPRSA also indicates that the LPRSA is unlikely to support more than a few mink. For example, use of the nearby Hackensack Meadowlands by mink is reported to be rare (Kiviat and MacDonald 2004), possibly due to limited woody vegetation. As stated in the FFS, future conditions are unlikely to change for the LPRSA, particularly in the lower 8.3 miles. Unless habitat conditions change, it is likely the mink will not be able to establish a breeding population within the LPRSA.

A habitat analysis is included as part of the CPG BERA (Windward 2014c). This analysis determined that 49 ha of patchily dispersed habitat are available within the LPRSA, when areas 100 ft from the shoreline are included (i.e., areas where most riparian habitat are present). When the amount of available habitat was compared to data from the literature on the amount of habitat needed per river mile of home range, results indicated that there is insufficient tree and shrub cover along any particular length of the LPRSA to support even a single reproducing female mink. In order to support a minimum viable population of 50 mink, it was estimated that habitat from an area extending more than 7 mi outward in all directions would be needed in addition to LPRSA habitat. The contribution of LPRSA habitat to the total amount of habitat needed for a minimum viable population is negligible.

7. AE(2) and AE(3) differ from the assessment endpoints identified in the PFD (Windward and AECOM 2009) and do not align with the fish assessment presented.

Section 4.1.4: Selection of Assessment Endpoints. The two fish groups identified are "demersal, benthinvertivorous fish" and "piscivorous or semi-piscivorous fish", but these do not align with the two fish groups evaluated: mummichog and generic fish. The generic fish category includes fish (i.e., carp) that do not frequently feed on fish. The following fish feeding guilds should be evaluated separately in the risk assessment in accordance with the PFD (Windward and AECOM 2009): benthic omnivores (e.g., mummichog), invertivorous fish (e.g., white perch), and piscivorous/semi-piscivorous fish (e.g., American eel).

8. The depth of the BAZ is not supported by site-specific data

Section 4.2 Ecological exposure assessment, p. 4-19. The FFS states that the sediment profile imaging survey conducted by Germano & Associates (2005) "determined that the apparent successional status of the benthic community was Stage I for all sampling stations with considerable variability in community parameters throughout the FFS Study Area....". However, review of results presented in the study (i.e., Table 2 and Figures 21a through 21d of the FFS) shows that the benthic community between RM 0 and RM 8.3 are in various stages (i.e., Stage I⇒II, Stage II, Stage II⇒III, Stage III and Stage I on III).

Section 4.2 Ecological exposure assessment, p. 4-19. The FFS cites AquaSurvey and Germano to say that the river in the FFS Study Area is in a state of flux due to substrate instability and that the estuarine benthic community is continually at risk of being buried by newly deposited sediments. The CPG agrees that the area between RM 0 and RM 8.3 (and in particular the area between RM 0 and RM 4) is in a state of frequent physical disturbance with some areas more stable than others. It is important to note that this condition will not be addressed through remediation, because tidal estuaries (and urbanized estuaries in particular), regardless of contamination, are subjected to such physical factors (or water quality factors such as turbidity and salinity).

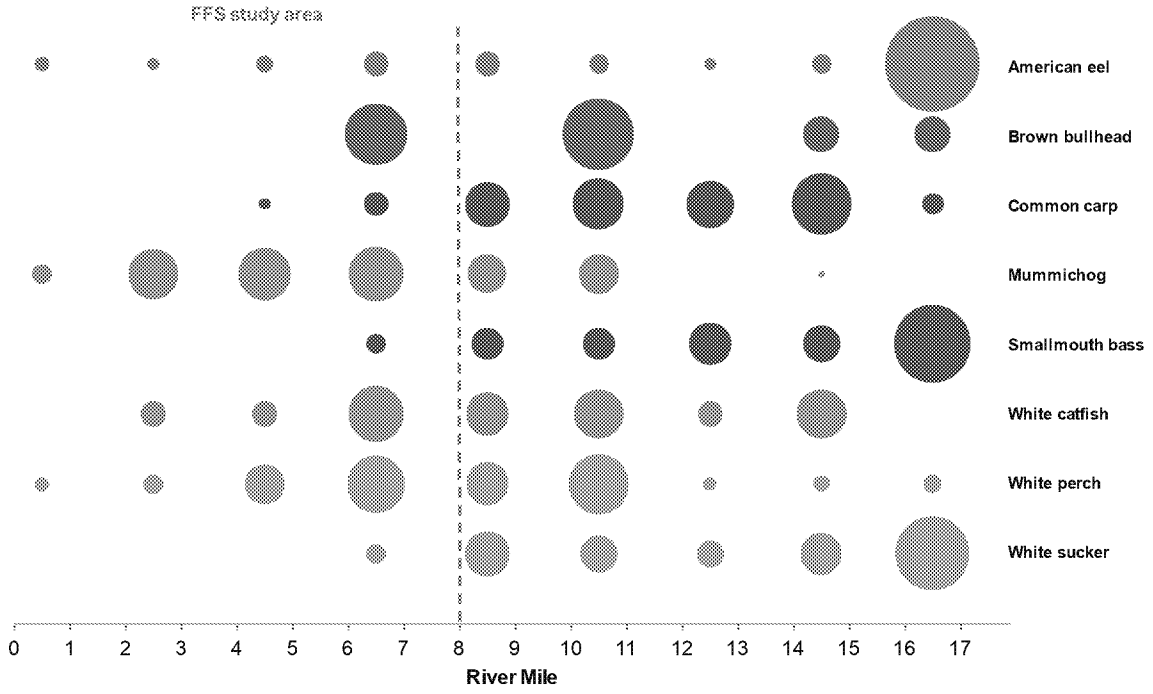
Section 4.2 Ecological exposure assessment, p. 4-19 to 4-20. Region 2 relies on data from Newark Bay (Diaz 2008) to determine that the BAZ for the LPR is 15 cm. However, site-specific data developed by Germano & Associates (2005) for the LPR identifies that almost all biological activity occurs in the aerobic zone that is limited to the upper few cm of the sediment surface (mean of 1.9 cm), and that there

is little evidence of biological activity extending below the aerobic zone (below the apparent redox potential discontinuity). Both the studies (Germano & Associates 2005; Diaz 2008) employed the same equipment and applied similar analytical approaches to the resulting data. Region 2 are familiar with the work and conclusions reported by Germano & Associates (2005) as the agency funded the work through the consultant group working on behalf of Region 2. The significance of the differences in the BAZ is important in understanding the exposure environment for the benthic community, which forms the basis for the majority of the food chain in the Passaic River. Germano & Associates (2005) noted the presence of benthic organisms at the sediment surface, or in the shallow sediment. Their presence in this shallow zone restricts chemical exposure to the more recently deposited sediment and the layer of unconsolidated material (i.e., fluff layer) common in salt wedge estuaries. Chemical concentrations in this shallow layer are predicted to be lower because on the contributions of offsite material.

9. The FFS Study Area is considered a single exposure point for the majority of receptors without consideration where salinity and habitat may limit the presence of some species.

Section 4.2.1: Ecological exposure areas, p. 4-20. For fish, only two of the fish species included in the "generic" fish category (American eel and white perch) were collected throughout the FFS Study Area. Other species are limited by salinity and were only present above RM 5 (carp and brown bullhead) or RM 7 (white sucker and smallmouth bass). The grouping of these fish to combine a single EPC for the entire 8.3-mile FFS study area is not appropriate and does not represent the accurate range of where these species are present.

For example, carp, the species with the highest concentrations for a number of key contaminants across all fish species collected in the LPR, were only found above RM 5 and by far the largest number of carp were collected above RM 8 (Figure 4). The inclusion of carp in a "generic fish" overstates fish tissue concentrations of key contaminants for other species in the lower 8.3 miles of the Passaic River. Smallmouth bass and white sucker, also included in the "generic fish," were only collected above RM 7 and do not reflect an exposure to the lower 8.3 miles of the LPR.



Note: Actual location of fish catch was rounded to the nearest river mile; the area of each bubble represents the percentage of each fish species caught per river mile.

Figure 4. Percentages of Fish Species Caught per River Mile in the LPRSA

For heron, limiting exposure to sediment only within mudflat areas of the lower 8.3 miles of the LPR is a reasonable assumption based on their feeding habits. Great blue heron were found throughout the LPRSA during the avian surveys (Windward 2011a, [in prep]-i; BBL 2002), and they showed no preference among fresh, brackish, or saltwater habitats (Kushlan 1978; Willard 1977; Chapman and Howard 1984). Great blue heron use both exposed sediment and shoreline and tend to hunt for prey only in shallow water. The inclusion of sediment from the entire FFS Study Area (p. 4-21, 2nd paragraph) is inconsistent with the following statement from p. 2-3: "Great blue heron are wading birds that feed on forage fish in mudflat areas, and are likely only to be exposed to mudflat sediments."

The assumption that mink could be present in the lower 8.3 miles of the LPR under current conditions is not appropriate (see specific Comment No. 6, above).

10. Additional tissue data should be included in the evaluation of invertebrate tissue EPCs (worm bioaccumulation tissue data and caged bivalve [mussel] tissue data).

Section 4.2.2: Benthic invertebrate EPCs. Worm bioaccumulation data were collected for the evaluation of potential risks to benthic invertebrates through the comparison of tissue concentrations to toxicity thresholds, as stated in the Region 2-approved QAPPs (Windward 2009b). Per Region 2's direction, caged bivalve tissue data were to be used to assess the effects of LPRSA chemicals through the use of tissue TRVs and chemistry data (Windward 2011b, [in prep]-e).

11. The use of "generic" fish to derive EPCs for fish is not appropriate.

Section 4.2.2: Fish EPCs. For risks to fish, tissue EPCs should be derived by species, or at a minimum, by feeding guild. For risks to receptors eating fish, tissue EPCs should be derived based on appropriately

sized fish prey. For heron, only forage fish should be evaluated (none of the generic fish represent appropriately sized fish [see specific Comment No. 5, above]). For mink, only fish ≤ 30 cm should be evaluated (see specific Comment No. 5, above), including mummichog, white perch, brown bullhead, and smallmouth bass. Forage fish and other fish should not be evaluated separately for mink, given that mink are opportunistic and will prey on available fish. Abundance of potential fish prey in the LPRSA should be taken into account to determine mink opportunistic diet. Table 3 presents a comparison of the FFS "generic fish" UCLs to appropriately sized fish UCLs for mink diet (i.e., fish ≤ 30 cm).

12. The assumptions used in the fish and bird egg modeling methods are based on generic assumptions rather than using site-specific and receptor-appropriate assumptions.

Section 4.2.3: Modeled Tissue Residues. For modeled fish eggs, site-specific mummichog egg lipid data are available from the lower 8.3 miles of the LPRSA. Ten samples were collected and analyzed; data are presented in Windward ([in prep]-c). The average LPR mummichog lipid value (3.1%) should be used to estimate mummichog egg concentrations rather than a generic lake trout lipid value (8.2%). Fish egg EPCs based on site-specific lipid data are presented in Table 4.

Table 4. Comparison of Estimated Fish Egg EPCs

	Fish Egg EPCs (µg/g)		
	Mummichog		Generic fish
COPEC	FFS EPC[b,c]	Revised EPC[d]	FFS EPC[a,e]
PCB TEQ	1.6×10^{-6}	6.0×10^{-7}	2.4×10^{-6}
PCDD/PCDF TEQ	1.4×10^{-4}	5.1×10^{-5}	2.4×10^{-4}
Total TEQ	1.4×10^{-4}	5.1×10^{-5}	2.4×10^{-4}

[a] From Table 5-1 of Attachment 5 of Appendix D of the FFS (Louis Berger et al. 2014) .

[b] From Table 5-2 of Attachment 5 of Appendix D of the FFS.

[c] FFS EPC for mummichog assumes egg lipid of 8.2% based on lake trout (Cook et al. 2003) and whole body lipid of 1.9% based on LPRSA mummichog.

[d] Revised EPC for mummichog assumes egg lipid of 3.1% and whole body lipid of 1.9% based on LPRSA mummichog.

[e] FFS EPC for generic fish assumes egg lipid of 8.2% based on lake trout (Cook et al. 2003) and whole body lipid of 5.9% based on LPRSA American eel and white perch and uses generic fish whole body EPCs.

Section 4.2.3: Modeled Tissue Residues. Fish eggs, p. 4-25. The evaluation of fish eggs is relevant only for receptors expected to spawn in the lower 8.3 miles of the LPRSA. Mummichog were the only fish species targeted for egg collection for lipid analysis for the LPRSA and therefore, the egg modeling should be limited to only mummichog. Furthermore, for the generic fish egg evaluation, it appears the FFS specifically includes American eel lipid-specific values to derive a generic fish egg concentration. American eel do not reproduce in the LPRSA; they are believed to occur in the Atlantic Ocean, specifically in the Sargasso Sea, (Brust 2006; NJDEP 2001).

Section 4.2.3: Modeled Tissue Residues: Avian eggs, pp. 4-25 and 4-26. For modeled bird eggs, the lipid values used in the modeling approach were based on herring gull egg lipid value (7.7%) from the literature (Braune and Norstrom 1989) and the lipid fish tissue value of generic fish (5.9%) from the lower 8.3 miles of the LPRSA. The bird egg model is based on several assumptions, including the primary or exclusive consumption of fish (bird egg biomagnification factors [BMFs] are based on fish and bird egg tissue relationships). Herring gulls were not a selected receptor for the LPRSA based on the PFD

(Windward and AECOM 2009). Other piscivore receptors (heron and kingfisher) were selected as representative piscivorous bird receptors in the LPRSA over herring gulls because herring gulls are opportunistic feeders with a highly variable portion of diet that is fish based on site-specific availability (Pierotti and Good 1992). The modeled bird egg evaluation should be based on the selected LPRSA receptor evaluated for the dietary assessment in the FFS (great blue heron). Therefore, a great blue heron egg lipid value should be used (5.7% based on Straub et al. [2007]) and a fish lipid value should be based on appropriately-sized prey (1.2% based on mummichog from the lower 8.3 miles of the LPRSA). Fish prey EPCs should be based on appropriately-sized fish for heron, therefore only mummichog EPCs should be used, not generic fish EPCs.

Receptor-specific BMFs should be used, when data are available (see the LPRSA BERA [Windward 2014c]). Revised bird egg EPCs based on appropriate lipid values and heron-specific BMFs were calculated and are presented in Table 5.

Table 5. Comparison of Estimated Avian Egg EPCs

Chemical	Avian Egg EPCs (µg/g)	
	FFS EPC[a]	Revised EPC[b]
Dieldrin	0.14	0.11
Total DDx	5.6	4.0
Total PCBs	47	9.3
PCB TEQ	1.7×10^{-3}	1.0×10^{-3}
PCDD/PCDF TEQ	2.3×10^{-3}	1.5×10^{-3}
Total TEQ	3.9×10^{-3}	2.6×10^{-3}

[a] FFS EPCs from Table 5-4 of Attachment 5 of Appendix D of the FFS (Louis Berger et al. 2014). FFS EPCs assumes egg lipid of 7.7% based on herring gull and fish lipid of 5.9% based on generic fish samples from lower 8.3 miles of LPR. Total TEQ was calculated as the sum of the individual PCB and PCDD/PCDF congener EPCs presented in Table 5-4.

[b] Revised EPCs assumes egg lipid of 5.7% based on great blue heron and fish lipid of 1.2% based on mummichog samples from lower 8.3 miles of LPR, and heron-specific BMFs

13. The FFS citation of regional cormorant egg tissue concentrations to justify the accuracy of modeled LPRSA egg tissue concentrations is invalid and inappropriate.

Section 4.2.3: Modeled Tissue Residues: Avian eggs, p. 4-26. The FFS states "Higher concentrations in the Passaic River samples would be expected and these comparison suggest that the modeling approach described is consistent with the available empirical data". The FFS incorrectly reported the concentrations of PCBs 77, 81, and 126 in cormorant eggs from Shooter's Island and instead reported the concentrations in egg plasma. The maximum egg concentrations from Shooter's Island for PCB 77, PCB 81, and PCB 126 are 0.0012, 0.0031, and 0.0049 µg/g, respectively, which are equal to or even higher than modeled LPRSA egg concentrations of 0.0012, 0.00015, and 0.00028 µg/g respectively. In addition, the maximum egg concentrations from Shooter's Island for 1,2,3,7,8-PeCDD and 2,3,4,7,8-PeCDF (which both have fish toxic equivalency factors [TEFs] of 1.0) are 0.000033 and 0.0000366 µg/g, respectively, are slightly higher than modeled LPRSA egg concentrations of 0.000012 and 0.000027 µg/g respectively. Therefore the quote above from the FFS stating that higher concentrations would be expected in LPRSA samples is not supported by the data from Parsons (2003) and based on the logic of the statement, instead leads to the conclusion that the modeling approach is inconsistent with empirical data.

Furthermore, the comparison of estimated herring gull egg concentrations based on LPRSA fish to cormorants from Shooter's Island based on Parsons (2003) to justify the egg model is consistent with empirical data is inappropriate. A comparison of fish prey tissue concentrations between the LPRSA and Shooter's Island would be more appropriate for determining whether the relative differences in egg concentrations are "supported" by empirical data. Differences in egg tissue concentrations between LPRSA gulls and Shooter's Island can also be attributed to differences in home range and feeding habits.

14. Assumptions used to calculate dietary doses should be transparent and accurate.

Section 4.2.4: Wildlife dietary model: Table 4-11. The calculated SIRs presented in Table 4-11 should be expressed as dry weight (dw) because sediment concentrations measured in the LPRSA are expressed as dw (tissue concentrations are expressed as ww). Assuming a moisture content of 74% (based on average moisture contents of blue crab [whole body] and fish tissue [whole body] collected between RM 0 and RM 8). Corrected SIRs are presented in Table 6.

Table 6. Corrected SIRs for Heron and Mink

Receptor	FIR (kg ww)/day[a]	FIR (kg dw)/day[b]	% SI[a]	SIR (kg dw)/day	SIR (kg ww)/day[a]
Great blue heron	**0.39**	0.101	5	**0.0051**	0.019
Mink	**0.17**	0.044	2	**0.00088**	0.003

Bold represents the appropriate FIR and SIR to use in risk calculations.

[a] From Table 4-11 of Appendix D of the FFS (Louis Berger et al. 2014) .

[b] Dry weight (dw) FIR determined assuming 74% moisture in prey (i.e., whole body fish and crab tissue samples from RM 0 – RM 8).

Section 4.2.4: Wildlife dietary model: Great blue heron, p. 4-27. In the absence of empirical data, best professional judgment should be used to estimate the incidental portion of sediment consumed by heron. Heron are not expected to consume high portions of sediment when capturing fish prey, which makes up most of their diet. Their incidental sediment is likely to be similar to or less than mink (2%).

15. The use of "generic" fish to derive fish prey EPCs for birds and mammals is not appropriate.

Section 4.2.4: Wildlife dietary model: Great blue heron, p. 4-28. Only mummichog EPCs (not generic fish EPCs) should be used in the risk calculations for heron and only mudflat EPCs (not site-wide sediment EPCs) should be used in the risk calculations for heron (see Specific Comment No. 5, above). Mudflat EPCs should include samples from an ecologically appropriate mudflat area, with justification for the selected mudflat samples.

Section 4.2.4: Wildlife dietary model: Mink, p. 4-28. The use of all generic fish is not appropriate for mink (see Specific Comment No. 5, above). Only fish ≤ 30 cm should be evaluated, including mummichog, white perch, brown bullhead, and smallmouth bass. Forage fish and other fish should not be evaluated separately for mink, given that mink are opportunistic and will prey on available fish. Abundance of potential fish prey in the LRRSA should be taken into account to determine mink opportunistic diet.

16. The FFS ERA misleadingly cites two studies (Wintermyer and Cooper 2003; Kubiak et al. 2007) as "site-specific" to derive technically indefensible invertebrate 2,3,7,8-TCDD CBRs and sediment thresholds that are inappropriate for characterizing risks to benthic invertebrates.

Section 4.3.1: Effects Data Evaluation, p. 4-29: Site-specific toxicity data were "not generally utilized", as stated in Section 4.3.1. The "sole exception" is the use of data from Wintermyer and Cooper (2003) to evaluate risk of 2,3,7,8-TCDD to oysters. The use of the Wintermyer and Cooper (2003) data to determine the 2,3,7,8-TCDD tissue threshold (and PRG) for benthic invertebrates is inappropriate.

The FFS ERA and Region 2's responses to recent the National Remedy Review Board's Contaminated Sediments Technical Advisory Group comments on the FFS (USEPA 2014b) misleadingly cite a study performed by Wintermyer and Cooper (2003) and "tabulated" by USFWS (Kubiak et al. 2007) as site-specific and "most appropriate for FFS remedial decision-making." The use of this single study has led Region 2 to derive technically indefensible invertebrate 2,3,7,8-TCDD CBRs and sediment thresholds that are wholly inappropriate for informing remedial decisions. This study results in the lowest sediment and tissue PRGs across all ecological receptors for 2,3,7,8-TCDD.

Tissue CBRs were derived from Wintermyer and Cooper (2003), wherein concentrations of PCBs and dioxins/furans were measured in oysters deployed at two locations near Newark Bay: one in Arthur Kill (Newark Bay estuary) and the other at Sandy Hook, New Jersey. The study appears to have based its conclusions on a single tissue sample (a composite of seven oysters) from each of the two sites. In the study, reproductive effects were evaluated by measuring the success rate of egg fertilization from a subset of the transplanted oysters and of normal early development (48 hours) of those fertilized eggs in a single test. This study, based on one sample (n = 1), does not provide any measure of variability in tissue concentrations, and no evidence is provided indicating that the findings are reproducible.

The sediment threshold for 2,3,7,8-TCDD was derived by USFWS (Kubiak et al. 2007) by poorly pairing the two tissue values for transplanted oysters reported in Wintermyer and Cooper (2003) (one from Arthur Kill and the other from Sandy Hook) with sediment data collected for the CARP. The sediment threshold was back-calculated by Kubiak et al. (2007) from the tissue concentrations by applying a BSAF that was calculated using only those same two tissue concentrations.

Clearly, in addition to the tissue thresholds being inappropriate for use as effect and no-effect thresholds (see above), the methods used by USFWS in the back-calculation misapplied the available data (i.e., using tissue and sediment data collected independently [i.e., not co-located] and for other purposes and combining them as pairs to calculate BSAFs). A single sediment sample collected from Arthur Kill was paired with one tissue sample result from a single location an unknown distance from where oysters were exposed (Wintermyer and Cooper 2003) to derive a BSAF. The sediment was not co-located with the tissue data and was from one sediment sample, failing to provide an indication of the variability in chemical concentrations. It appears a BSAF was also calculated for Sandy Hook, but the location of the "co-located "sediment used to derive this BSAF is not even provided.

EPA has provided methodology and guidelines for developing BSAFs (Burkhard 2009), which stress the importance of using data with similar underlying conditions (both ecological and chemical). According to EPA, "*mixing of C_{soc}-C_l* (sediment and tissue) *paired observations with different underlying conditions is not recommended and will, in all likelihood, result in BSAFs with poor predictive accuracy.*" Judd et al. (2013) evaluated a large BSAF data set from EPA's Mid-Continent Ecology Division and demonstrated that biota-sediment relationships cannot be assumed to be linear, and that basing decisions on BSAFs focused on one chemical is highly uncertain. The use of only two paired observations to develop a sediment benchmark (and ultimately a cleanup goal) is not defensible.

17. The use of LRM data to establish sediment thresholds for defining risks to benthic invertebrates is not appropriate

Section 4.3.1: Effects Data Evaluation. The LRM classifies samples as either toxic or non-toxic based on statistical comparison to negative control data and <90% survival. In their comments to the draft PFD for the Newark Bay Study Area (Tierra Solutions 2013), Region 2 commented, "Use of control sediment is for QA/QC purposes; not for making site-related decisions. Ecological risk decisions should be based on responses relative to reference and concentration-response relationships." Thus, it is inappropriate and overly conservative to use a model based on comparison to negative control data for making management decisions.

18. The use of ER-L and ER-M values is not appropriate for a baseline risk assessment for determining-site-specific risks when site-specific data are available (see Specific Comment No. 2, above on Section 4.1.3).

Section 4.3.2: Stressor-Response Profiles. Sediment Benchmarks, pp. 4-30 and 4-31. The use of ER-L and ER-M values is not appropriate for a baseline risk assessment for determining-site-specific risks when site-specific data are available (see Specific Comment No. 2, above on Section 4.1.3).

Section 4.3.2: Stressor-Response Profiles. Sediment Benchmarks, pp. 4-30 and 4-31. The sediment benchmark developed for 2,3,7,8-TCDD based on the study by Wintermyer and Cooper (2003) is also inappropriate (see previous comment). The FFS cites the *Fish and Decapod Field Report for the Late Summer/Early Fall 2009 Field Effort* (Windward 2010c) to establish oyster as an appropriate endpoint species because the report documents the presence of oysters in the LPRSA. The citation is incorrect. Oysters are not mentioned in the report cited and oysters were not observed during the weeks of surveying that was conducted for the fish community, benthic community, or habitat identification.

- A small number of Eastern oyster (*Crassostrea virginica*) individuals were identified in benthic community samples collected in the LPRSA during the spring and summer 2010 survey events (Windward 2014d); only one individual was identified in spring samples (from RM 4.16), and 8 were identified in summer samples from RM 3.39 (7 individuals) and RM 4.16 (1 individual). None were identified in the larger number of samples collected during the fall 2009 benthic community survey.
- Eastern oysters are not expected to successfully colonize the LPRSA upstream of approximately RM 4, due to fluctuations in seasonal salinity that exceed their tolerance. Puglisi (2008) notes that salinities below 10 ppt (and above 28 ppt) are suboptimal for Eastern oyster growth and reproduction, and that salinities below 6 ppt impede metamorphosis of larvae to spat. Interstitial salinity measured during the LPRSA SQT sampling event in 2009 (Windward [in prep]-a) was less than 10 ppt as far downstream as RM 1.6 and less than 6 ppt as far downstream as RM 3.39. Interstitial salinities did not exceed 6 ppt above RM 4.19 (Windward [in prep]-a). During a pilot study in which caged Eastern oyster were deployed in the LPRSA at RM 3.9 and RM 6.8 (Windward 2011d), oysters were able to survive at RM 3.9, but substantial mortality (61%) was observed at RM 6.8. Based on direct observations of the benthic invertebrate community, observed mortality at approximately RM 6.8, and physiological information from the literature, it is concluded that Eastern oyster are unlikely to colonize areas of the LPRSA upstream of approximately RM 4 and may be stressed between approximately RM 0 and RM 4 as a result of shifting seasonal salinities in that area.
- Because the FFS Study Area is "in a state of flux due to substrate instability and (the estuarine benthic) community is continually at risk of being buried by newly deposited sediments" it will be difficult for oysters to establish a stable, long-term population.
- Region 2's use of the PRG for 2,3,7,8-TCDD, based on (Wintermyer and Cooper 2003), is not relevant for the entire FFS assessment area, because Eastern oysters are not expected to be present in much of the area (between approximately RM 4 and RM 8.3).

- Interestingly, the sediment PRG for 2,3,7,8-TCDD proposed in the FFS that is intended to provide a protective level for invertebrates affected adversely from sediment concentrations derived from this calculation (3 ppt dw) is similar to the background values reported from Mullica River/Great Bay, an area considered by Region 2 to represent rural background conditions. This would therefore indicate that the concentrations of 2,3,7,8-TCDD found in rural estuarine locations in NJ would result in reproductive failure in oysters. The presence of robust oyster beds in NJ estuarine waters demonstrates this is not the case.

19. The FFS uses inappropriate and technically indefensible toxicity thresholds without justification or basis for selection

Section 4.3.1: Effects Data Evaluation, p. 4-29: Measurement endpoints are stated as "focused on the population level consequences of COPEC exposure resulting in reduced survival, growth, or reproduction of receptors of concern." However, several of the selected thresholds are based on non-standard endpoints that do not represent a direct, measurable effect of exposure on survival, growth or reproduction (e.g., altered behavior).

Section 4.3.2: Stressor-Response Profiles. Critical Body Residues, pp. 4-32 through 4-38. Tables 7, 8, and 9 present specific comments to CBRs for invertebrates, fish adults, and fish eggs, respectively.

Section 4.3.2: Stressor-Response Profiles. Toxicity Reference Values, pp. 4-38 through 4-44. Tables 10, 11, and 12 present specific comments to TRVs for birds diet, bird egg, and mammal diet, respectively.

General comments to the selected CBRs and TRVs are as follows:

- *Justification of selected CBRs/TRVs.* The justification of selected CBRs/TRVs FFS is not clearly documented or justified.
- *Use of field studies*: Field studies were used in some cases to derive TRVs [e.g., the benthic invertebrate 2,3,7,8-TCDD CBR based on Wintermyer and Cooper (2003)]. CBRs/TRVs should be derived from controlled toxicity studies that used standardized and/or peer-reviewed experiment methods, in which a clear concentration- or dose-response relationship was reported. This principle generally excludes the use of field studies.
- *The evaluation of metals and PAHs using a CBR approach:* As stated in footnote e of Table 5-2 in the Region 2-approved PFD (Windward and AECOM 2009), for chemicals that are metabolized or otherwise regulated by fish, a tissue respond approach is not appropriate. Tissue body burdens of most metals are biologically regulated, and because of the wide range of strategies used by aquatic organisms to store, detoxify, and excrete bioaccumulated metals, it is difficult to develop broadly applicable tissue residue toxicity thresholds for these organisms for metals (except mercury and selenium). Furthermore, metals uptake rates, which strongly influence whether bioavailable metals levels in tissue may be toxic, are influenced by site-specific factors (Adams et al. 2011).In addition, the use of the CBR approach for most metals is contrary to USEPA (2007b), which states: "For metals (aside from organo-selenium and methyl mercury), the situation is far more complex [than organic chemicals] and the CBR approach does not appear to be a robust indicator of toxic dose". USEPA (2007b) further states: "Although many toxicological studies report measurements of metal residues in multiple tissues along with adverse effects, these tissue residue values may not be appropriate for use as a CBR threshold because metal concentrations in some tissues may have little or no relationship with toxicity." Thus, the use of CBRs for copper, lead, and PAHs is not appropriate.
- *The use of extrapolation factors:* Rationale for the application of extrapolation factors is unsatisfactory; use of "best professional judgment" in the selection of uncertainty factors is not well justified. For example, exposure duration and severity of effect appears to have been reasons for using extrapolation factors, however, definitions of acute, subchronic, and chronic are

not explicit. Extrapolation factors are highly uncertain and are not recommended for the derivation of CBRs/TRVs, especially without a detailed uncertainty discussion of them and the HQs derived from them.

- *Use of chicken reproductive toxicity studies:* TRVs for birds should not be based on egg productivity or other reproductive endpoints in a domesticated species, such as chickens or Japanese quail. Comparing toxic threshold effects on reproductive endpoints for these species with reproductive endpoints for non-domesticated species is problematic because of differences in reproductive physiology. In addition, chickens are known to be highly sensitive to PCBs and dioxin-like compounds. Toxicity data from studies with chickens are likely to overpredict PCDD/PCDF sensitivity to LPRSA species, such as the great blue heron (which is in the low sensitivity group).
- *Lack of discussion on TRV uncertainties:* The uncertainty discussion of TRVs is inadequate for a baseline risk assessment. Uncertainties associated with specific CBR/TRVs suggest that they are inappropriate for use in a baseline risk assessment (see TRV Tables 7 through 11).
- *Use of multiple species to derive CBRs/TRVs*: Risk thresholds were generally single species-based threshold values, with the exception of several tissue residue TRVs (Beckvar et al. 2005; Steevens et al. 2005; USEPA 2003), which were based on 5th percentile values of species sensitivity distributions (SSDs). Detailed toxicity data evaluations, such as with dose-response relationships or SSDs, are more appropriate in the evaluation of baseline risks and should be used to derive CBRs and TRVs where data are appropriate (e.g., for fish CBRs and total PCBs and 2,3,7,8-TCDD).
- *Invertebrate CBRs:* Due to the differences in toxicity among invertebrate species, decapod-specific TRVs are recommended where toxicity data are available.
- *Use of EPA ecological soil screening level (ECO-SSL) documents.* TRVs obtained directly from EPA Eco-SSL documents are based on values from studies that were not independently reviewed. Some of these studies are not readily available through online databases. CPG does not recommend use of TRVs if the primary source cannot be obtained for review. As stated in EPA guidance "*U.S. EPA discourages reliance on secondary references because study details relevant for determining the applicability of findings to a given site usually are not reported in secondary sources. Only primary literature that has been carefully reviewed by an ecotoxicologist should be used to support a decision*" (USEPA 1997)
- *General presentation and consistency:* Throughout Section 4.3.2, there are a number of inconsistencies among tables and text as well as editorial issues that reduce the overall transparency of the selected CBRs/TRVs. These include the following examples:
  - Identifying the exact source and derivation for many CBRs/TRVs proved convoluted in a number of case. A number of the derived CBRs/TRVs could not be replicated using the information provided in Section 4.3.2, Table 6-1, and the original source (if available) (e.g., invertebrate total PCB CBRs; see Tables 7 through 11 for specific TRV comments).
  - Inconsistencies between information presented in Section 4.3.2 and Tables 6-1 and 6-2 of Attachment 6. These inconsistencies include differences between explanations of threshold derivation methods. For example, the text in Section 4.3.2 describes use of both a 10-fold "subchronic-to-chronic" extrapolation factor (i.e., UFC) and a 5-fold "interspecific EF" (i.e., UFI)to derive the 2,3,7,8-TCDD avian dietary LOAEL/NOAEL, while Table 6-2 shows only the 5-fold UFI. As another example, the text in Section 4.3.2 discussing the 2,3,7,8-TCDD (TEQ) fish tissue CBR states that the CBRs are based on measured larval fish tissue concentrations, when in actuality they are interpolated values, as described in Table 6-1.
  - Typos and errors within Table 6-1 and 6-2 of Attachment 6. For example, "Sample et al. 1966" was cited as a primary source for total DDx dietary TRVs for mammals, which should be "Sample et al. 1996". For the same TRV, the notes in Table 6-2 indicate the EPA Eco-SSL document as the source of the TRVs, which is incorrect. As another example of a copy-paste

error, the notes in Table 6-1 for the 2,3,7,8-TCDD fish embryo CBR incorrectly reference a source table from the primary source of the avian embryo CBR.

Table 7. Evaluation of LPRSA FFS-proposed Benthic Invertebrate Tissue TRVs

COI	Test Species	NOAEL (mg/kg ww)	LOAEL (mg/kg ww)	Endpoint	Source	Appropriate BERA TRV?	Rationale
Copper	clam	5	12	survival	Absil et al. (1996)	No	A tissue-residue approach is not recommended for the evaluation of metals (other than mercury and selenium) in tissue.
Lead	freshwater amphipod	0.52	2.6	survival	Borgmann & Norwood (1999)	No	A tissue-residue approach is not recommended for the evaluation of metals (other than mercury and selenium) in tissue. In addition, the use of extrapolation factors is not recommended (LOAEL is based on a LOAEL divided by an interspecies factor of 2 and NOAEL is based on adjusted LOAEL divided by 5).
Mercury/ Methyl-mercury	estuarine copepod	0.048	0.095	reproduction	Hook and Fisher (2002)	Yes	The FFS CBRs are acceptable for the evaluation of non-decapod invertebrate tissue in the FFS ERA. CBRs for decapod species are also available and would be more appropriate for evaluation of blue crab tissue. The LPRSA BERA used a LOAEL of 1.0 mg/kg ww in hepatopancreas tissue based on crab survival (Bianchini and Gilles 1996) and a NOAEL of 0.34 mg/kg ww in muscle tissue based on lobster survival (Canli and Furness 1995) for the evaluation of mercury in blue crabs.
LPAHs	estuarine polychaete	0.078	0.78	reproduction	Emery and Dillon (1996)	No	FFS LPAH CBRs are not appropriate because reported effect (of anthracene) was not clearly adverse compared to the environmentally-relevant seawater control (a 35% decrease in growth and fecundity were reported at the LOAEL relative to carrier control [acetone], but was not different from seawater control). In addition, the NOAEL was extrapolated from LOAEL by a factor of 10. LPAHs were not a COPEC for benthic invertebrate tissue in the LPRSA BERA. In Appendix A to the LPRSA BERA, a LOAEL of 25 mg/kg ww based on survival of polychaetes (Morales-Caselles et al. 2008) and a NOAEL of 3.58 mg/kg ww based on survival of zebra mussels (Roper et al. 1997) were used. Individual PAH TRVs can also be used for comparison to individual PAHs measured in LPR benthic invertebrate tissue.

Table 7. Evaluation of LPRSA FFS-proposed Benthic Invertebrate Tissue TRVs

COI	Test Species	NOAEL (mg/kg ww)	LOAEL (mg/kg ww)	Endpoint	Source	Appropriate BERA TRV?	Rationale
HPAHs	blue mussel	0.022	0.22	reproduction	Eertman et al. (1995)	No	FFS HPAH CBRs are not appropriate because LOAEL is based on the fluoranthene concentrations in mussels in which the effects on abnormal gametogenesis were observed; however, this endpoint is not a direct measure of reproductive success. In addition, no statistically significant differences were reported; study concluded that "the reproductive success rate of mussels appeared to be affected negatively". NOAEL was extrapolated from LOAEL by a factor of 10. HPAHs were not a COPEC for benthic invertebrate tissue in the LPRSA BERA. Appendix A to the LPRSA BERA evaluated total PAHs in benthic invertebrate tissue (see above).
Total PCBs	eastern oyster	0.008	0.026	reproduction	(Chu et al. 2000; Chu et al. 2003)	No	FFS CBRs are not appropriate because tissue concentrations were not measured in the study where adverse effects were observed. The CBRs are estimated tissue concentrations based on an interpolation. The interpolation was based on the maximum egg tissue concentrations measured in Chu et al. (2000) for daily doses of 1 and 0.1 µg PCBs and the lowest daily dose from (Chu et al. 2003), and assumes a linear relationship between the dose and egg tissue concentration. The studies did not use the same experiment design (i.e., different doses and exposure durations). The interpolation could not be recreated to check the calculation of the LOAEL egg concentration (400 ng PCB/egg) based on the information provided in Appendix D and the individual studies. Total PCBs were not a COPEC for benthic invertebrate tissue in the LPRSA BERA. In Appendix A to the LPRSA BERA, a LOAEL of 1.1 mg/kg based on grass shrimp survival based on Hansen et al. (1974) was used. This was also the LOAEL used in the original 2007 draft of the FFS.

Table 7. Evaluation of LPRSA FFS-proposed Benthic Invertebrate Tissue TRVs

COI	Test Species	NOAEL (mg/kg ww)	LOAEL (mg/kg ww)	Endpoint	Source	Appropriate BERA TRV?	Rationale
Dieldrin	pink shrimp	0.01	0.08	survival	Parrish et al. (1973) as cited in Louis Berger et al. (2014)	No	Parrish et al. (1973) was not available for review. TRVs are not recommended if the primary source cannot be reviewed and the reported values verified. It should be noted that this source is not a peer-reviewed study as it appears to be based on conference proceedings. In addition, the use of extrapolation factors is not recommended (NOAEL is based on NOAEL divided by 10 because exposure was acute [i.e.,96 hours]). Dieldrin was not a COPEC for benthic invertebrate tissue in the LPRSA BERA. In Appendix A to the LPRSA BERA. a LOAEL of 4.78 mg/kg based on midge survival (Estenik and Collins 1979) was used.
Total DDx	pink shrimp	0.060	0.13	survival	Nimmo et al. (1970)	Yes	The total DDx CBRs are acceptable, although there are uncertainties associated with this study (high mortality in the control [17%]) that should be discussed.
2,3,7,8-TCDD	eastern oyster	1.5×10^{-7}	1.3×10^{-6}	reproduction	Wintermyer and Cooper (2003)	No	See text for specific comments. 2,3,7,8-TCDD was not a COPEC for benthic invertebrate tissue in the LPRSA BERA. In Appendix A to the LPRSA BERA, a LOAEL of 3.0×10^{-3} mg/kg based on crayfish survival Ashley et al. (Ashley et al. 1996) was used.

Table 8. Evaluation of LPRSA FFS-proposed Fish Tissue TRVs (Louis Berger et al. 2014)

COI	Test Species	NOAEL (mg/kg ww)	LOAEL (mg/kg ww)	Endpoint	Source	Appropriate BERA TRV?	Rationale
Whole-body TRVs							
Copper	striped mullet	0.32	1.5	survival	Zyadah and Abdel-Baky (2000)	No	A tissue-residue approach is not recommended for the evaluation of metals in tissue and not supported by USEPA (2007b) as a reliable measure of toxicity, especially when extrapolating across different exposure routes (i.e., aqueous dissolved copper exposure in study to dietary/sediment exposure in the LPRSA). In addition, the use of extrapolation factors is not recommended (LOAEL is based on LOAEL divided by 5) and the extrapolated LOAEL (1.5 mg/kg ww) is lower than the reported 24 hr NOAEL in the paper (1.6 mg/kg ww).
Lead	rainbow trout	0.4	4.0	reproduction	Holcombe et al. (1976)	No	A tissue-residue approach is not recommended for the evaluation of metals in tissue and not supported by USEPA (2007b) as a reliable measure of toxicity, especially when extrapolating across different exposure routes (i.e., aqueous dissolved copper exposure in study to dietary/sediment exposure in the LPRSA). In addition, the use of extrapolation factors is not recommended (NOAEL is based on LOAEL divided by 10).
Mercury/ Methyl-mercury	various	0.052	0.26	growth, survival, reproduction, and behavior	Beckvar et al. (2005)	No	The use of an SSD is appropriate for determining a mercury CBR for fish; however, the FFS-recommended CBRs are inappropriate because the LOAEL is based on a 5th percentile that includes toxicity studies that are not appropriate for the development of baseline ERA TRVs. The three lowest LOAELs used in Beckvar et al. (2005) are not appropriate as detatiled in Windward ([in prep]-I): • A LOAEL of 0.25 mg/kg based on walleye reproduction (Friedmann et al. 1996) is not appropriate because the whole body tissue concentrations were not reported (LOAEL is whole body tissue concentration without the viscera). • A LOAEL of 0.3 mg/kg based on striped mullet development (Weis and Weis 1978) is not appropriate because the relevance of the effect (regeneration of an amputated caudal fin) is questionable for evaluating survival, growth, and

Table 8. Evaluation of LPRSA FFS-proposed Fish Tissue TRVs (Louis Berger et al. 2014)

COI	Test Species	NOAEL (mg/kg ww)	LOAEL (mg/kg ww)	Endpoint	Source	Appropriate BERA TRV?	Rationale
							reproduction in the LPR. • A LOAEL of 0.56 mg/kg based on fathead minnow reproduction (Hammerschmidt et al. 2002) should be used instead of the LOAEL of 0.39 mg/kg ww reported in Beckvar et al. (2005). In addition, the use of extrapolation factors is not recommended (NOAEL is based on LOAEL divided by 5). In the LPRSA BERA, a LOAEL of 0.37 mg/kg was selected as the TRV based on the 5th percentile SSD from toxicity data on survival, growth, reproduction, and/or behavior directly relevant to survival of12 fish species.
LPAHs	fathead minnow	0.26	2.6	reproduction	Hall and Oris (1991)	No	Tissue-residue TRVs are not applicable for PAHs in fish because they are rapidly metabolized and excreted by fish following uptake.
HPAHs	Pacific sand sole	0.21	2.1	mortality	Hose et al. (1982)	No	Tissue-residue TRVs are not applicable for PAHs in fish because they are rapidly metabolized and excreted by fish following uptake.
Total PCBs	Atlantic salmon	0.17	0.53	behavior (smolt seawater preference)	Lerner et al. (2007)	No	FFS-recommended CBRs are inappropriate because the behavioral endpoint and receptor evaluated (seawater preference for smolting salmon) are not relevant to the LPRSA, selected fish receptors and assessment endpoints (survival, growth, and reproduction). The LPRSA BERA used a total PCB TRV based on an SSD is recommended. A LOAEL of 6.3 mg/kg based on the 5th percentile SSD from toxicity data on survival, growth and/or reproduction of 11 fish species.
Dieldrin	rainbow trout	0.008	0.040	survival	Shubat and Curtis (1986)	No	Shubat and Curtis (1986) is an acceptable study for development of the TRVs. However, FFS-recommended TRVs were extrapolated on the basis that a 4-month study was not chronic. The EF cited as used (an EF of 2 is cited in Table 6-1 of Attachment 6 of FFS Appendix D) does not result in the FFS-recommended TRVs. Dieldrin was not a COPEC for fish in the LPRSA BERA. In Appendix A to the LPRSA BERA, the reported LOAEL and NOAEL of 0.2 and 0.12 mg/kg, respectively, from Shubat

Table 8. Evaluation of LPRSA FFS-proposed Fish Tissue TRVs (Louis Berger et al. 2014)

COI	Test Species	NOAEL (mg/kg ww)	LOAEL (mg/kg ww)	Endpoint	Source	Appropriate BERA TRV?	Rationale
							and Curtis (1986) were used.
Total DDx	various	0.078	0.39	growth, survival, reproduction, and behavior	Beckvar et al. (2005)	No	The use of an SSD is appropriate for determining DDx CBR for fish; however, the FFS-recommended TRVs are not acceptable because the LOAEL is based on a 5th percentile that includes toxicity studies that are not appropriate for the development of baseline ERA TRVs. The three lowest LOEALs used in Beckvar et al. (2005) are not appropriate as detatiled in Windward ([in prep]-I): • A LOAEL of 1.65 mg/kg based on goldfish behavior (Davy et al. 1972) is not appropriate because the effect measured (locomotor activity) is not a direct measure of survival, growth, or reproduction (the assessment endpoints). • A LOAEL of 0.55 mg/kg based on pinfish survival (Butler 1969) is not appropriate because the effect (survival) was not tissue concentration-dependent; concentrations were higher (2.7 mg/kg ww) than this LOAEL in surviving fish. • A LOAEL of 0.29 mg/kg based on lake trout survival (Berlin et al. 1981) is not appropriate because is based on field collected eggs from Lake Michigan where high concentrations of PCBs, DDx and mercury were reported in the eggs prior to the evaluation of effects. In addition, the use of extrapolation factors is not recommended (NOAEL is based on LOAEL divided by 5). Total DDx was not a COPEC for fish in the LPRSA BERA. In Appendix A to the LPRSA BERA, a LOAEL (and NOAEL) of 1.8 mg/kg based on cutthroat trout survival based on Allison et al. (1964) was used. Allison et al. (1964) is also included in the evaluation as a LOAEL used by Beckvar et al. (2005), although a slightly lower LOAEL (1.1 mg/kg) is reported.
2,3,7,8-TCDD	mummichog	8.9×10^{-7}	1.8×10^{-6}	behavior (prey capture ability,	Couillard et al. (2011)	No	FFS-recommended TRVs are not acceptable. The use of a relatively non-toxic dioxin-like congener (PCB 126) to establish a TRV for 2,3,7,8-TCDD is inappropriate. There are high uncertainties associated with fish TEFs established

Table 8. Evaluation of LPRSA FFS-proposed Fish Tissue TRVs (Louis Berger et al. 2014)

COI	Test Species	NOAEL (mg/kg ww)	LOAEL (mg/kg ww)	Endpoint	Source	Appropriate BERA TRV?	Rationale
				growth)			by Van den Berg et al. (1998). In addition, the paper did not measure tissue concentrations in mummichog; tissue concentrations were linearly interpolated for topical doses of 25 and 50 pg/L based on one empirical data point (100 pg/L topical dose and a mean 710 pg/g larvae tissue) measured in a previous study, Couillard et al. (2008), as cited in Couillard et al. (2011). Furthermore, the FFS-reported tissue concentrations appear to have been erroneously calculated from due to discrepancy between units of the values selected from Couillard et al. (2011) in the interpolation. The use of behavior studies not directly measuring survival, growth, and reproduction is also questionable for the evaluation of the selected assessment endpoints. The LPRSA BERA used a 2,3,7,8-TCDD LOAEL of 1.53 x 10^{-4} mg/kg based on the 5th percentile SSD from toxicity data on survival, growth and/or reproduction of 8 fish species.
Egg TRVs							
2,3,7,8-TCDD	Various	7.2 x 10^{-6}	8.6 x 10^{-5}	survival, reproduction	Steevens et al. (2005)	Yes	The use of an SSD is appropriate for determining fish egg 2,3,7,8-TCDD CBR for fish and agrees with the TRVs reported in the FFS document are appropriate. The LPRSA BERA used a LOAEL of 3.9 x 10^{-5} mg/kg ww based on the 5th percentile of toxicity data for 11 species.

Table 9. Evaluation of LPRSA FFS-proposed Bird Egg Tissue TRVs (Louis Berger et al. 2014)

COI	Test Species	NOAEL (mg/kg ww)	LOAEL (mg/kg ww)	Endpoint	Source	Appropriate BERA TRV?	Rationale
Dieldrin	barn owl	0.20	8.1	reproduction	Mendenhall et al. (1983)	Yes (LOAEL as NOAEL)	FFS-recommended TRVs are not appropriate because the endpoint at the LOAEL (shell thickness reduced by 5.5%) is not a direct measure or reproduction and is not clearly an adverse effect. Dieldrin was not a COPEC for bird egg tissue in the LPRSA BERA. It would be more appropriate to use the LOAEL (8.1 mg/kg ww) from Mendenhall et al. (1983) as a NOAEL because the LOAEL is not clearly an adverse effect.
Total DDx	brown pelican	0.5	3.7	reproduction (eggshell thickness)	Blus (1984)	No	FFS-recommended TRVs are not appropriate because the toxicity data used in the cited paper are based on field collected eggs with other reported contaminants in tissues. The exposure of field organisms to multiple contaminants complicates the direct linkage between field effects observed (eggshell thinning) and tissue residue concentrations of single contaminants (DDE). Total DDx was not a COPEC for bird egg tissue in the LPRSA BERA. In Appendix A to the LPRSA BERA, a LOAEL of 12 mg/kg ww based on barn owl reproduction based on Mendenhall et al. (1983) was used.
Total PCBs	chicken	0.7	1.3	reproduction	Chapman (2003)	No	FFS-recommended TRVs are not appropriate because values the NOAEL and LOAEL are based on an interpolated threshold that includes chicken reproduction (hatchability) toxicity. TRVs based on domestic reproductive endpoints are not appropriate because domesticated species such as chickens (and quails) have altered egg-laying rates compared to wild bird species. The LPRSA BERA used a LOAEL TRV for total PCBs of 16 mg/kg ww based on ringed turtle dove reproduction as reported in Peakall et al. (1972); Peakall and Peakall (1973).

Table 9. Evaluation of LPRSA FFS-proposed Bird Egg Tissue TRVs (Louis Berger et al. 2014)

COI	Test Species	NOAEL (mg/kg ww)	LOAEL (mg/kg ww)	Endpoint	Source	Appropriate BERA TRV?	Rationale
PCDD/ PCDFs	various	5.9×10^{-5}	1.5×10^{-4}	various	USEPA (2003)	No	The use of an SSD is appropriate for determining egg 2,3,7,8-TCDD CBR for birds; however, the inclusion of chicken reproductive toxicity data in the SSD is not appropriate. TRVs based on domestic reproductive endpoints are not appropriate because domesticated species such as chickens (and quails) have altered egg-laying rates compared to wild bird species. In addition, bird species have been found to be highly variable in their sensitivity to dioxin-like compounds. Recent studies have found that avian sensitivity to the toxic effects of dioxin-like compounds may vary by up to 1,000-fold among bird species, and is associated with differences in the structural characteristics of the AH receptor (Farmahin et al. 2013; Cohen-Barnhouse et al. 2011; Head et al. 2008). Genetic differences in the ligand-binding domain of the AH receptor have been correlated to differences in avian sensitivities, such as embryo survival (Head et al. 2008). Using the amino acid sequences of the ligand-binding domain of the AH receptor in individual bird species, birds have been grouped into three classifications of sensitivity to dioxin-like compounds: 1) high sensitivity, 2) moderate sensitivity, and 3) low sensitivity (Farmahin et al. 2013). Chickens are in the high sensitivity group and likely overpredict PCDD/PCDF sensitivity to LPRSA species, such as the great blue heron, which are in the low sensitivity group. The LPRSA BERA used a 2,3,7,8-TCDD LOAEL of 8.6×10^{-4} mg/kg based on the 5th percentile SSD of reproductive (egg) toxicity data from 5 bird species.

Table 10. Evaluation of LPRSA FFS-Proposed Bird Diet TRVs (Louis Berger et al. 2014)

COI	Test Species	NOAEL (mg/kg bw/ day)	LOAEL (mg/kg bw/ day)	Endpoint	Source	Appropriate BERA TRV?	Rationale
Copper	turkey	2.3	4.7	growth	Kashani et al. (1986) as cited in USEPA (2007a)	No	These TRVs appear to have been taken from the EPA Eco-SSL document without primary review. The LOAEL TRV is based on a 3.3% decrease in body weight compared to the control at 8 weeks, with a recovery in body weight at 12 weeks, and no effect on body weight at 16, 12 , and 24 weeks. This effect result does not indicate a level at which adverse effects would be expected and should not represent a LOAEL for use in a risk assessment. The LPRSA BERA used a LOAEL of 19 mg/kg bw/day based on a growth endpoint in chickens from Jensen and Maurice (1978).
Lead	quail	0.19	1.9	reproduction	Edens & Garlich (1983) as cited in USEPA (2005a)	No	These TRVs appear to have been taken from the EPA Eco-SSL document without primary review. They are based on an egg production endpoint in quail, which are a domesticated species that have been bred to have high egg-laying rates. These TRVs should not be applied in risk assessment because they are not representative of effects to wild birds. The LPRSA BERA used NOAEL and LOAEL TRVs or 5.5 and 28 mg/kg bw/day, respectively, based on a growth endpoint for Japanese quail (Morgan et al. 1975).

Table 10. Evaluation of LPRSA FFS-Proposed Bird Diet TRVs (Louis Berger et al. 2014)

COI	Test Species	NOAEL (mg/kg bw/ day)	LOAEL (mg/kg bw/ day)	Endpoint	Source	Appropriate BERA TRV?	Rationale
Mercury	mallard duck	0.013	0.026	reproduction	Heinz 1974, 1975, (1979), as cited in USEPA (1995)	No	Heinz (1979) is an acceptable study for development of the screening-level LOAEL, but a 3-fold interspecies extrapolation factor is overly conservative. No rationale is provided in the FFS for the assumption that mallard is three times more sensitive than the avian wildlife receptor (i.e., great blue heron) evaluated in the FFS. In addition, a reproductive NOAEL for mallards based on Heinz (1974; 1976) is available and therefore a NOAEL based on empirical data is preferred rather than the use of a LOAEL-to-NOAEL conversion factor of 2. The LPRSA BERA used a LOAEL of 0.064 mg/kg bw/day derived from Heinz (1979) and equivalent to the LOAEL provided in Sample et al. (1996), and a NOAEL of 0.050 mg/kg bw/day, derived from Heinz (1974, 1976).

Table 10. Evaluation of LPRSA FFS-Proposed Bird Diet TRVs (Louis Berger et al. 2014)

COI	Test Species	NOAEL (mg/kg bw/ day)	LOAEL (mg/kg bw/ day)	Endpoint	Source	Appropriate BERA TRV?	Rationale
LPAHs	red winged blackbird	0.67	6.7	survival	Schafer et al. (1983)	No	The FFS TRV is based on an acute (48-hr) study based on gavage-exposure to individual LPAH compounds (acenaphthene, fluorene, phenanthrene and anthracene). The LOAEL was calculated from a LD-50 value with an acute to chronic ratio of 5 and an interspecies factor of 3. This is not an appropriate BERA TRV because of uncertainties associated with the exposure by gavage and the application of a toxicity value for one PAH compound to a mixture of LPAHs which assumes that the potency of all the individual compound s in the mixture are equivalent. In addition, no rationale is provided for the assumption that red-winged blackbird is three times more sensitive than the avian wildlife receptor (i.e., great blue heron) evaluated in the FFS. Exposure to PAHs should be evaluated based on the form that was used in the toxicity test. CPG is not aware of an acceptable LOAEL TRV for an individual LPAH or a mixture of LPAHs. However, there is a NOAEL of 2,000 mg/kg bw/day for naphthalene and a NOAEL of 40 mg/kg bw/day that can be used for total PAHS based on a study with a mixture of PAHs, as were used in Appendix A to the LPRSA BERA.

Table 10. Evaluation of LPRSA FFS-Proposed Bird Diet TRVs (Louis Berger et al. 2014)

COI	Test Species	NOAEL (mg/kg bw/ day)	LOAEL (mg/kg bw/ day)	Endpoint	Source	Appropriate BERA TRV?	Rationale
HPAHs	pigeon	0.048	0.48	reproduction	Hough et al. (1993)	No	Hough et al. (1993) is an appropriate source of a TRV for benzo(a)pyrene, but the use of an interspecies uncertainty factor of 3 is inappropriate. No rationale is provided for the use of this factor. In addition, CPG does not agree with the use of the LOAEL-to-NOAEL uncertainty factor of 10. The LPRSA BERA used a LOAEL from Hough et al. (1993) of 1.4 mg/kg bw/day for exposure to benzo(a)pyrene only.
Dieldrin	crowned guinea fowl	0.054	0.18	survival	Wiese et al. (1969) as cited in USEPA (2007a)	No	This TRV appears to have been taken from EPA SSL document for use in the FFS because the original paper could not be obtained. The selected value is the lowest value of 56 papers reviewed for TRVs associated with reduced reproduction, growth and mortality in whole body birds. TRVs from Wiese et al (1969) for reproductive effects are higher than the mortality TRV from the paper selected by EPA. This paper could not be obtained for review, so CPG is not able to determine whether it is acceptable for use as a TRV. Dieldrin was not a COPEC for bird diet in the LPRSA BERA. In Appendix A to the LPRSA BERA, a NOAEL and LOAEL of 0.080 and 0.12 mg/kg bw/day based on a survival endpoint in quail (DeWitt 1956) were used.

Table 10. Evaluation of LPRSA FFS-Proposed Bird Diet TRVs (Louis Berger et al. 2014)

COI	Test Species	NOAEL (mg/kg bw/ day)	LOAEL (mg/kg bw/ day)	Endpoint	Source	Appropriate BERA TRV?	Rationale
Total DDx	brown pelican	0.00090	0.027	reproduction	Anderson et al. (1975) as cited in USEPA (1995)	No	These TRVs are not appropriate because the LOAEL was not derived from a controlled toxicological study where effects can be related to exposure to DDx. Anderson et al. (1975) was a field study that compared observations about productivity and eggshell thinning seen in site location to standards known to support a stable population. No analysis was performed to determine significance of changes (in eggshell thinning and productivity) and no consideration was made to the effects that may have been a result of exposure to multiple chemicals which is likely in field situations. In addition, CPG does not agree with the extrapolation of the NOAEL from the LOAEL. Total DDx was not a COPEC for bird diet in the LPRSA BERA. In Appendix A to the LPRSA BERA, a LOAEL of 0.90 mg/kg bw/day was derived from Heath et al. 1969 because it was a controlled long-term (2 year) study that reported effects on reproduction after exposure to DDT, DDE, or DDD.

Table 10. Evaluation of LPRSA FFS-Proposed Bird Diet TRVs (Louis Berger et al. 2014)

COI	Test Species	NOAEL (mg/kg bw/ day)	LOAEL (mg/kg bw/ day)	Endpoint	Source	Appropriate BERA TRV?	Rationale
Total PCBs	chicken	0.4	0.5	reproduction	Chapman (2003)	No	The FFS-recommended TRVs are not appropriate because they are based on interpolated values from thresholds based on chicken reproduction, which is not appropriate because domesticated species such as chickens have altered egg-laying rates compared to wild bird species. The LPRSA BERA used a LOAEL TRV of 1.4 mg/kg bw/day be used; this TRV is based on a reproductive endpoint in ringed turtle dove (Peakall et al. 1972; Peakall and Peakall 1973).
2,3,7,8-TCDD	pheasant	2.8×10^{-6}	2.8×10^{-5}	reproduction	Nosek et al. (1992) as cited in USEPA (1995)	No	The FFS TRVs are not appropriate due to the use of a 5-fold factor to account for data indicating that pheasants are not among the most sensitive species (Farmahin et al. 2013). Of 86 birds tested by Farmahin et al. (2013), chickens and 4 other species (red jungle fowl, European starling, ruby-throated hummingbird, and gray catbird) were considered to fall within Group 1, containing species most sensitive to dioxin-like compounds. Ring-necked pheasant, the species used in this TRV study, falls within Group 2 (with lower sensitivity than Group 1) along with spotted sandpiper and 45 other species, primarily songbirds. Great blue heron falls into Group 3, indicating it is less sensitive than pheasants. Therefore, it is not considered appropriate to reduce this TRV by a factor of five; conversely, this TRV is likely conservative when applied to great blue heron. Also, it should be noted that the text stated that a 10-fold chronic-to subchronic extrapolation factor was applied but this is not reflected in Table 6-2. The LPRSA BERA used the original NOAEL and LOAEL of 1.4×10^{-5} and 1.4×10^{-4} from the study by Nosek et al. (1992) without the use of an uncertainty factor.

Table 11. Summary of TRVs for Mammal Diet Recommended in the LPRSA FFS

COI	Test Species	NOAEL (mg/kg bw/ day)	LOAEL (mg/kg bw/day)	Endpoint	Source	Appropriate BERA TRV?	Rationale
Copper	mink	3.4	6.8	reproduction	Aulerich et al. (1982) as cited in USEPA (2007a)	No	These TRVs were obtained from the EPA Eco-SSL document. Aulerich et al. (1982) is an appropriate study for development of the TRVs but different values from the cited study should be used in place of those selected in the FFS. The LOAEL of 6.8 was derived from the conclusion that adverse effects were observed at 25 ppm in the diet. However, at this concentration there were no statistically identified effects on kit mortality or growth and no clear dose-response associated with the number of kits whelped per female. Kit weight was significantly lower than the control at 100 ppm in the diet and percent mortality was clearly higher at this dose (although statistics were not provided). Therefore, the dietary concentration of 100 ppm should be used to derive the LOAEL, rather than 25 ppm. Copper was not a COPEC for mammal diet in the LPRSA BERA. In Appendix A to the LPRSA BERA, NOAEL and LOAEL TRVs of 18 and 26 mg/kg bw/day, respectively, were derived from Aulerich et al. (1982) using the dietary concentration of 100 ppm as the low effect level.
Lead	rat	0.71	7.0	reproduction	Grant et al. (1980) as cited in (USEPA 2005a)	No	These TRVs were obtained from the EPA Eco-SSL document and are not appropriate because of the uncertainty in the use of drinking water as the mode of uptake. The bioavailability of lead in water may be substantially higher than in prey items, which is the primary form of exposure considered in the risk assessment. The available toxicity data for food exposure should be used instead of data for drinking water exposure. Lead was not a COPEC for mammal diet in the LPRSA BERA. In Appendix A to the LPRSA BERA, the NOAEL and LOAEL TRVs were 11 and 90 mg/kg bw/day, respectively, based on a growth endpoint in rats (Azar et al. 1973).

Table 11. Summary of TRVs for Mammal Diet Recommended in the LPRSA FFS

COI	Test Species	NOAEL (mg/kg bw/ day)	LOAEL (mg/kg bw/day)	Endpoint	Source	Appropriate BERA TRV?	Rationale
Mercury	mink	0.0016	0.027	growth	Wobeser et al. (1976a,b) as derived in USEPA (1995)	No	Wobeser et al. (1976a,b) is an appropriate study for development of the TRVs but the use of a 10-fold subchronic-to-chronic uncertainty factor is not appropriate for a BERA. Sufficient information is not available to conclude that the dose applied in the study would result in effects at a dietary concentration ten time lower (i.e., at 0.18 ppm) if exposure was longer. Previous studies by the same author did not find any effects of feeding mink diets of up to 75% of fish containing 0.44 ppm over a 145-day period. The NOAEL and LOAEL TRVs from Wobeser et al. (1976a,b) would be appropriate to use without the 10-fold factor. Mercury was not a COPEC for mammal diet in the LPRSA BERA, but similar values were derived from Wobeser et al. (1976a,b) for use in Appendix A to the LPRSA BERA.
LPAHs	rat	50	150	growth	Navarro et al. (1991) as cited in USEPA (2007b)	Yes	These TRVs were obtained from the EPA Eco-SSL document. These TRVs are appropriate for naphthalene alone but are not appropriate to evaluate the sum of LPAHs. Effects from PAH exposure should be evaluated based on the form that was used in the toxicity test.
HPAHs	mouse	0.62	3.1	growth	Culp et al. (1998) as cited in USEPA (2007b)	No	These TRVs were obtained from the EPA Eco-SSL document. These TRVs are not appropriate because the mice in this study were exposed to a PAH mixture, but only the value for benzo(a)pyrene was used to calculate the TRV. When the total PAH concentration was calculated using data presented in the study (Culp et al. 1998) the NOAEL and LOAEL TRVs for the growth endpoint were 30 and 61 mg/kg bw/day, respectively. HPAHs were not a COPEC for mammal diet in the LPRSA BERA. Appendix A to the LPRSA BERA used a benzo(a)pyrene LOAEL TRV of 10 mg/kg bw/day based on a reproductive endpoint in rats. This TRV should be compared to the exposure dose of benzo(a)pyrene and not to total HPAHs.

Table 11. Summary of TRVs for Mammal Diet Recommended in the LPRSA FFS

COI	Test Species	NOAEL (mg/kg bw/ day)	LOAEL (mg/kg bw/day)	Endpoint	Source	Appropriate BERA TRV?	Rationale
Dieldrin	rat	0.015	0.030	reproduction	Harr et al. (1970) as cited in USEPA (2005a)	Yes	These TRVs were used in the LPRSA BERA and are appropriate for the FFS ERA.
Total DDx	rat	0.80	4.0	reproduction	Fitzhugh (1948) as cited in (Sample et al. 1996)	Yes	These TRVs are appropriate for the FFS ERA. They were used in Appendix A to the LPRSA BERA.
Total PCBs	mink	0.069	0.082	reproduction	Chapman (2003)	Yes	This is an appropriate source for the TRVs and was used to derive TRVs in the LPRSA BERA, although slightly different NOAELs and LOAELs (0.080 and 0.096 mg/kg bw/day) were derived using a food ingestion rate of 0.16 g/g bw.
PCDDs/ PCDFs	mink	8.0×10^{-8}	2.2×10^{-6}	reproduction	Tillett et al. (1996)	No	FFS-recommended TRVs are not appropriate because the TRV are based on mink exposed to field-collected fish in their diet. Field collected fish may have contained other contaminants; therefore it is impossible to determine if impacts to the mink were solely due to PCDD exposure in their diet. TRVs based on a controlled mink study are recommended. The LPRSA BERA used a NOAEL and LOAEL of 2.6×10^{-6} and 8.8×10^{-6} mg/kg bw/day, respectively, based on a reproductive endpoint in a controlled laboratory study with mink (Hochstein et al. 2001).

20. The calculated risk estimates highly overestimate risks to ecological receptors based on generic and inappropriate exposure and effects assumptions.

Section 4.4. Risk characterization, p. 4-44. The FFS risk characterization is incomplete for metals which results in risk estimates for metals that are overstated and unreliable.

- **Lack of regional tissue evaluation for metals**: In their assessment of ecological risks to fish and crabs from copper and lead, Region 2 failed to consider that the copper and lead concentrations in fish and crabs from the lower 8 miles of the LPR are not elevated above regional levels of these metals in fish and crab. The CPG compared Region 2's fish and crab EPCs to regional concentrations of copper and lead in fish and crab published by EPA. Fish and crab regional concentrations were obtained from the Northeast 2000-2006 Summary Database from the EPA National Coastal Assessment website (http://www.epa.gov/emap2/nca/html/data/index.html). Because the EPA National Coastal Assessment database does not contain data for mummichog, comparative regional data for copper in mummichog was located in Chernoff and Dooley (1979), while adequate lead concentration data in mummichog was not found. Table 12 shows the comparison of the FFS reported EPCs and the calculated 95th percentile concentration from regional data and clearly shows that the Region 2 copper and lead EPCs are comparable to concentrations in fish and crab tissues caught elsewhere in the US northeast coastal region. This comparison illustrates that the concentration of lead and copper in fish and crab in the lower 8 miles are not elevated above regional levels. Further, this comparison also highlights that the CBRs used by Region 2 to predict an ecological risk to these fish and crabs are simply untenable given the presence of similar concentrations of these metals in aquatic species outside the lower 8 miles of the LPR. In other words, if Region 2's toxicity values were indicative of harm, essentially all fish and crabs in coastal northeastern waters would be facing a comparable ecological risk due to copper and/or lead, and there is no evidence to suggest such a finding. As part of their assessment of fish and crab tissue data, Region 2 should have compared copper and lead concentrations to northeast regional coastal fish and crab data. If this had been done, these metals would have been determined to be comparable with regional concentrations, and not have been identified as COCs with risks resulting from site-specific sources.

Table 12. Comparison of Copper and Lead Concentrations in Fish from the LPR and Other Locations in Northeastern Coastal Region

Metal	Species	Concentration (mg/kg)					
		Regional Data					USEPA (2014) FFS, App D, Table 4-1
		n	Min	Max	Ave	95 UCL	95 UCL
Copper	Fish[a]	150	0.005	163	9.93	16.1	12
	Crab[a]	75	1.2	66	24.6	26.7	24
	Mummichog[b]	132	na	na	7 to 10[c]	na	3.1 (2.77[d])
Lead	Fish[a]	153	0.005	5.28	0.38	0.57	0.5
	Crab[a]	75	0.005	3.4	0.56	0.67	0.37

[a] Source: National Coastal Assessment, Northeast 2000-2006 Summary Data, Fish and Crab Tissue Concentration Data, collected from locations in CT, DE, MA, NH, NJ, NY, PA, RI, and VA. 'Fish' includes the following species: Atlantic croaker, Atlantic tomcod, channel catfish, porgy, scup, spot, summer flounder, weakfish, white catfish, white perch, and winter flounder.

[b] Source: Great South Bay data from Chernoff, B. and J.K. Dooley. 1979. Heavy metals in relation to the biology of the mummichog, *Fundulus heteroclitus*. J. Fish Biol. 14, 309-328.

[c] Corresponding copper sediment concentration is 18±1 ppm.

[d] The average concentration is shown in parenthesis for comparison to the central tendency measurements of the regional data.

- **Lack of evaluation of meals bioavailability and bioaccessibility:** Region 2 neglects to consider bioavailability and bioaccessibility of metals in contravention of well-established agency guidance documents – specifically, EPA's *Framework for Metals Risk Assessment* (USEPA 2007b) and EPA's *Guidelines for Ecological Risk Assessment* (USEPA 1998). As a result of this omission, the FFS conclusions regarding the alleged contributions of metals in LPR sediment to risk are overstated, unreliable, arbitrary, and capricious. In order to properly gauge risk due to metals in sediment, "[r]isk assessors should adjust bulk metal concentrations by appropriate bioavailability factors to achieve comparable, actual uptake of metals by organisms." (USEPA 2007b). It is a widely accepted principle that metals exist in a variety of forms (chemical species) in sediment. Certain of these species are bioavailable and therefore toxic, while others are not. As a result, only a fraction of total metal concentration in sediment could actually contribute to metal toxicity in an ecosystem. Furthermore, USEPA (2007b) requires consideration of bioaccessibility. In order for a metal to contribute to risk, it must actually be accessible to and come into contact with an ecologic receptor: "A proper risk assessment should summarize the paths of stressors from the source to the receptors; if exposure can occur through many pathways, it should attempt to assess contribution of each pathway to total exposure" (USEPA 1998).

  USEPA (2007b) provides that the bioavailability and bioaccessibility of metals, and consequently, the associated risk, vary widely according to the physical, chemical, and biological conditions under which an organism is exposed. To the extent that available data and methods allow, the (USEPA 2007b) instructs that the risk assessor should explicitly incorporate factors that influence the bioavailability and bioaccessibility of a metal into risk assessment determinations. Despite readily available data in the record, however, Region 2's FFS risk assessment ignores such considerations explicitly set forth in its own guidance, including:

  – The form of the metal (chemical species, compound, matrix, and particle size) which influences the metal's bioaccessibility, bioavailability, fate, and effects

- Environmental properties which influence the form of the metal, such as pH, particle size, moisture, redox potential, organic matter, cation exchange capacity, and acid volatile sulfides (AVS/SEM)
- Exposure pathways (e.g., via water or diet) and their respective contribution to total exposure
- Physiological or anatomical characteristics of ecologic receptors which may regulate and/or store certain metals up to certain exposure levels without a toxic effect.

Accordingly, Region 2's reliance on the assumption that all metals in sediment were both toxic and available would tend to overstate the metals impact on LPR fish. Region 2's substantial departure from its own guidance contained without a logical explanation renders the FFS arbitrary and capricious. This erroneous deviation from sound NCP practice is further aggravated by Region 2's substitution for a standard bioavailability and exposure pathway analysis of metals in sediment with the inappropriate use of a CBR approach to metals risk assessment (see specific Comment No. 19). As a result, Region 2's conclusions regarding the alleged risk due to metals in LPR sediment are overstated and unreliable. Region 2's attribution of metals risk to a sediment source is arbitrary in the absence of support in the form of a proper metals risk assessment. In contrast to the FFS ERA, the CPG's BERA, formulated under Region 2 oversight and submitted to Region 2 in June 2014, uses all available site-specific data (which accounts for site-specific bioavailability) and complies with all applicable guidance in assessing metals bioavailability and metals exposure pathways. The CPG BERA properly concludes that metals in LPR sediment have little to no significant impact on LPRSA ecologic receptors.

Section 4.4.1. Benthic Invertebrate Hazard Estimates: Sediment Benchmarks, p. 4-45. Sediment benchmarks used to determine sediment HQs for invertebrates are not appropriate (see Specific Comment No. 2, above on Section 4.1.3). An SQT analysis for the Passaic River has been completed by the CPG using an approach approved by Region 2 and is presented in the draft BERA (2014). All of the site-specific data from the lower 8.3 miles of the Passaic River used in the BERA (2014) were presented to the Region 2 in multiple documents (Windward 2014a, [in prep]-k, a) and was known to Region 2 during development of the FFS ERA (as evidenced by inclusion in the FFS of the surface sediment chemistry data from the site-specific data reports produced by the CPG). If the FFS ERA had conducted an SQT analysis using the Region 2-approved CPG-generated SQT data, instead of conducting just a simple screening level assessment by comparing surface sediment chemistry data to generic sediment quality values, the FFS would have arrived at a far different conclusion concerning potential risks to the benthic community. In stark contrast to the conclusions in the FFS ERA, the following is a summary of key findings of the SQT analysis conducted in a similar manner to the BERA but specific to the lower 8.3 miles of the Passaic River:

- **Benthic community metrics**: Benthic community metrics for the lower 8.3 miles of the Passaic River were compared to benthic community metric data from Jamaica Bay, a reference area for the estuarine portion of the Passaic River that Region 2 directed the CPG to use in the BERA for defining risks to the benthic community. Of the 49 locations sampled in 2009 in the lower 8.3 miles of the Passaic River from which estuarine benthic community data were collected, only 2 locations exhibited differences in benthic community metrics from those in the Jamaica Bay reference area. The 2 locations, one at RM 5 and the other at RM 7, were only different from the reference data for a limited number of benthic community metrics. Benthic community metrics from all other estuarine locations in the lower Passaic River were within the range of conditions observed in the Jamaica Bay data.
- **Toxicity test response data:** Toxicity test data for samples collected in the estuarine portions of the lower 8.3 miles of the Passaic River were similar to toxicity response data from Jamaica Bay. Of the 27 locations sampled in 2009 with toxicity test data for *Ampelisca abdita* survival only 2 locations exhibited reduced survival compared with data from the Jamaica Bay reference area. The 2 locations are highly localized (e.g., immediately above RM 3.5) and not representative of the entire FFS study area. All other estuarine locations sampled in the lower Passaic River exhibited toxicity responses that were within the range of toxicity responses observed in Jamaica Bay data.

- **Sediment chemistry**: As noted earlier in this comment, sediment quality guideline values should not be used for purposes other than conducting a screening analysis of the data. Wetherington et al. (2005) and O'Connor et al. (1998), among others, have demonstrated that ER-Ms are highly unreliable (e.g., have high false positive rates) for predicting the toxicity of chemicals in sediment. An analysis of the reliability of the sediment benchmarks presented in the FFS for correctly predicting toxicity in the FFS study area relative to reference conditions (Table 13) demonstrates that the sediment quality guideline values used in the FFS ERA to define risks to the benthic community only correctly predicted toxicity between 7 and 12 percent of the time. These results demonstrate that sediment chemistry alone (based on comparison to generic sediment quality guideline values) is not a reliable determinant of potential risks to the benthic community. Even when sediment chemistry data are used in conjunction with more direct measures of potential risks to the benthic community (i.e., benthic community metrics and sediment toxicity test data) it does provide confirmation to the observations made using the direct measures.

As would be expected given its physical setting, the benthic community structure in the LPRSA is generally consistent with urban reference conditions. A comparison of LPRSA benthic community metrics with the reference data indicates that the benthic community in the estuarine and transitional salinity zones (typical of the lower 8 miles) exhibit few differences when compared with other urban, less contaminated estuaries indicating that the LPRSA benthic community is responding to typical urban stresses.

Table 13. Reliability of FFS Sediment Screening Criteria for Predicting Toxicity for *A. abdita* Survival

Chemical	Unit	Low Screening Criteria[a]		High Screening Criteria[a]	
		Value	Positive Predictive Power[b]	Value	Positive Predictive Power[b]
Copper	mg/kg	94	7.7 %	32	8.3 %
Lead	mg/kg	94	7.4 %	30	8.3 %
Mercury	µg/kg	480	7.7 %	140	7.7 %
Total HPAHs	µg/kg	9,600	7.4 %	1700	7.7 %
Total LPAHs	µg/kg	3,200	7.4 %	550	11.8 %
Total PCB congeners	µg/kg	370	7.7 %	35	8.0 %
2,3,7,8-TCDD	ng/kg	3.2	7.4 %	na	8.0 %
Dieldrin	µg/kg	2.9	8.0 %	0.83	10.5 %
Total DDx	µg/kg	46	7.4 %	1.6	8.0 %

Note: Analysis based on 27 locations below RM 8.3 that were considered estuarine during the 2009 RI/FS sampling (i.e., salinity < 0.5 ppt), and for which the *A. abdita* 10-day survival test was conducted. Test results were compared with reference area data from Jamaica Bay.

DDD = dichlorodiphenyldichloroethane
DDE = dichlorodiphenyldichloroethylene
DDT = dichlorodiphenyltrichloroethane
FFS = focused feasibility study
HPAH = high-molecular-weight polycyclic aromatic hydrocarbon
LPAH = low-molecular-weight polycyclic aromatic hydrocarbon
PCB = polychlorinated biphenyl
ppt = parts per thousand
RI/FS = remedial investigation/feasibility study
RM = river mile
TCDD = tetrachlorodibenzo-*p*-dioxin
total DDx – sum of all six DDT isomers (2,4′-DDD, 4,4′-DDD, 2,4′-DDE, 4,4′-DDE, 2,4′-DDT and 4,4′-DDT)

Chemical	Unit	Low Screening Criteria[a]		High Screening Criteria[a]	
		Value	Positive Predictive Power[b]	Value	Positive Predictive Power[b]

[a] As cited in the FFS, Table 4-12.

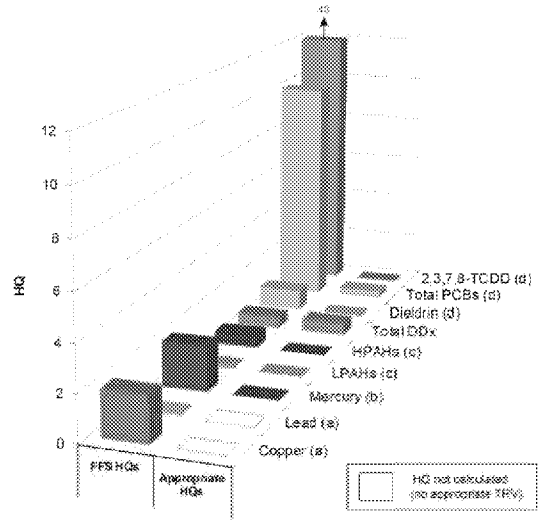
[b] The positive predictive power is calculated as the number of correctly predicted results divided by the number of samples predicted to be toxic using the sediment benchmarks presented in the FFS.

The results of the SQT analysis for the lower 8.3 miles using the SQT data generated by the CPG from Region 2-approved QAPPs, show that the impacts to the benthic community are limited to localized areas of the estuarine portion of the LPR. Of the all of the SQT locations within the lower 8.3 miles, only a small subset shows a moderate likelihood for benthic impact as compared with reference conditions; as discussed in CPG's BERA, these impacts are not directly related to chemistry. If the FFS had implemented an SQT analysis that evaluated the benthic data types listed in the Region 2-approved problem formulation rather than conducting a simple screening-level assessment, it would have arrived at a far different conclusion concerning potential risks to the benthic community. In stark contrast to the proposed bank-to-bank remedy, the SQT analysis would have confirmed the efficacy of a targeted approach.

Section 4.4.1. Benthic Invertebrate Hazard Estimates: Critical Body Residues, p. 4-46. HQs based on appropriate invertebrate CBRs (including decapod-specific CBRs, where toxicity data are available) are presented in Figure 5.

Section 4.4.2. Fish Hazard Estimates, pp. 4-47 and 4-48. Whole-body fish HQs based on appropriate EPCs (on a species-specific basis and excluding carp) and fish CBRs are presented in Figures 6 and 7. Fish egg HQs based on appropriate EPCs modeled using site-specific and species-specific tissue data) and fish egg CBRs are presented in Figure 8.

Section 4.4.3. Wildlife Hazard Estimates, pp. 4-48 through 4-51. Bird egg HQs based on appropriate EPCs (using appropriately sized fish), species-specific lipid values and BMFs, and bird egg TRVs are presented in Figure 9. Wildlife dietary HQs based on appropriate EPCs (using appropriately-sized prey) and TRVs are presented in Figures 10 and 11.



Note: FFS LOAEL HQs as reported in Table 4-15 of Appendix D. Appropriate LOAEL HQs based on FFS EPCs reported for blue crab (reported in Table 4-1 of Appendix D [Louis Berger et al. 2014]) and revised TRVs (see Table 7).

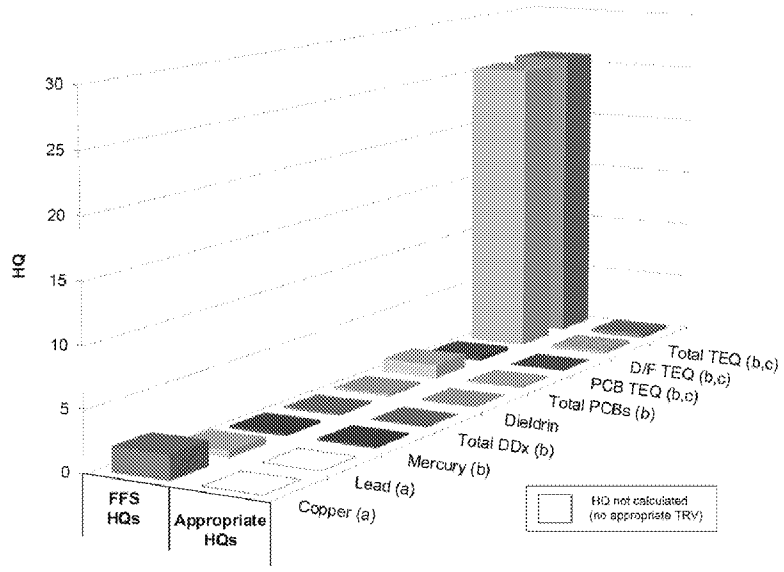
[a] Tissue-residue based TRVs for regulated metals are not recommended (see specific comments).

[b] Appropriate HQs are based on decapod-specific TRVs (see Table 7). Blue crab muscle-only and hepatopancreas-only tissue EPCs are 0.19 and 0.049 mg/kg ww, respectively, for methylmercury.

[c] Appropriate HQ is based on a TRV for total PAHs (see Table 7).

[d] Unbounded LOAEL TRV.

Figure 5. Blue Crab Tissue LOAEL HQs



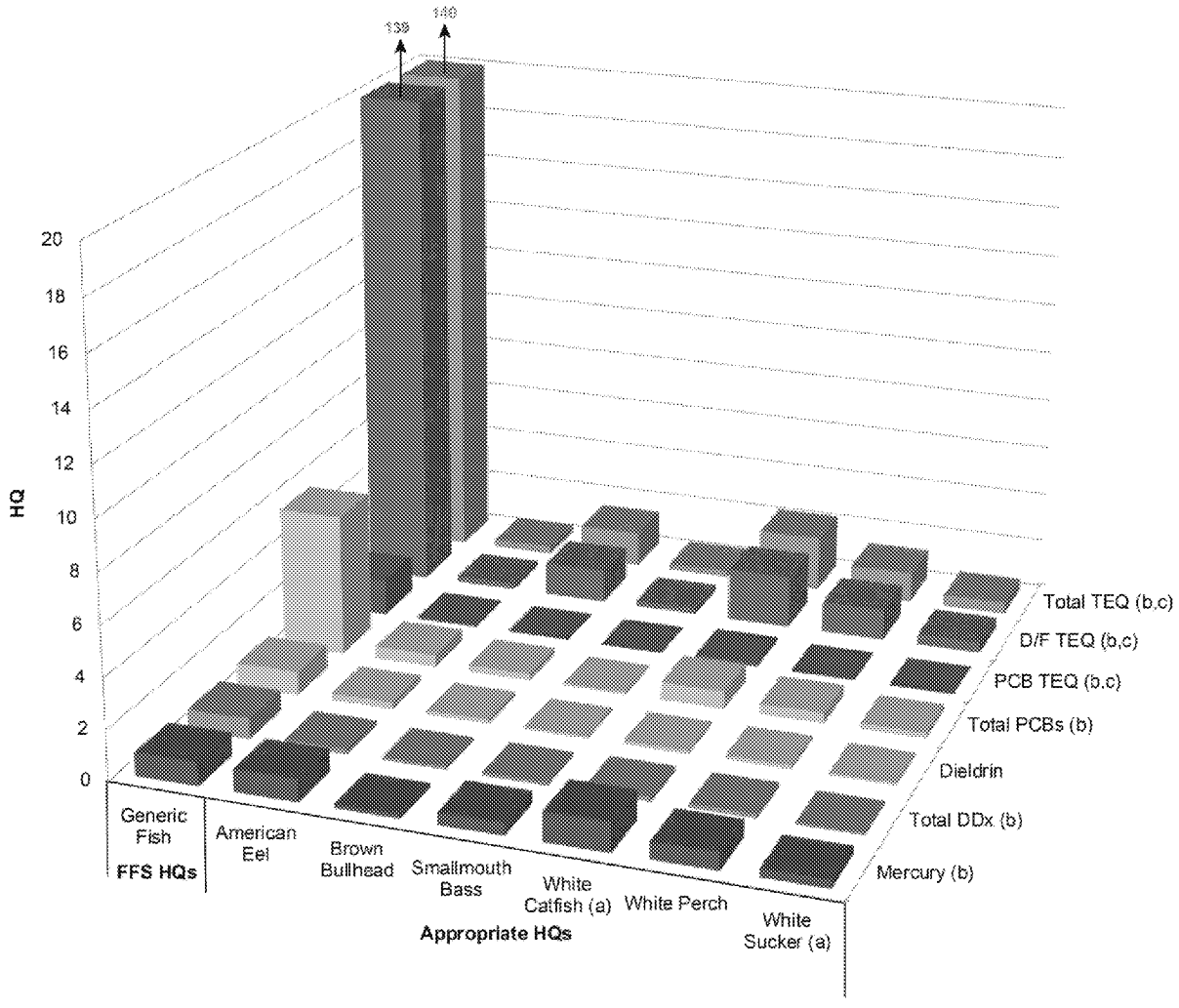
Note: FFS LOAEL HQs as reported in Table 4-15 of Appendix D. Appropriate LOAEL HQs based on FFS EPCs reported for mummichog (reported in Table 4-1 of Appendix D [Louis Berger et al. 2014]) and revised TRVs (see Table 8).

[a] Tissue-residue based TRVs for regulated metal or PAHs are not recommended (see specific comments).

[b] Unbounded LOAEL TRV.

[c] FFS total TEQ HQs are based on the sum of PCB and PCDD/PCDF TEQ EPCs; appropriate total TEQ HQs are based on EPCs calculated by CPG.

Figure 6. Mummichog Tissue LOAEL HQ



Notes:

-FFS LOAEL HQs as reported in Table 4-15 of Appendix D. Appropriate LOAEL HQs based on CPG-calculated EPCs for individual fish species (ProUCL recommended UCL or maximum concentration if n > 6 values) and revised TRVs (see Table 8).

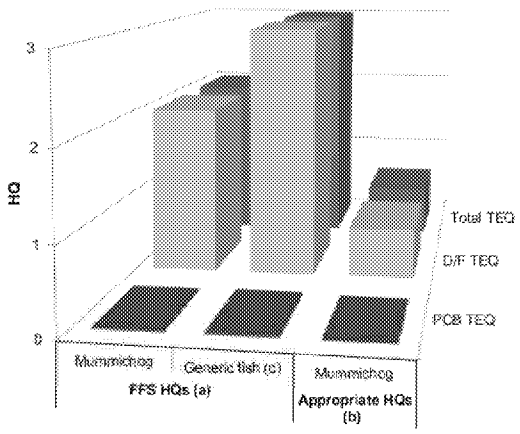
-Tissue-residue based TRVs for regulated metal or PAHs are not recommended (see specific comments), so FFS LOAEL HQs for copper, lead, LPAHs, and HPAHs are not shown.

[a] White catfish and white sucker were not selected as ecological receptors in the PFD (Windward and AECOM 2009), but can be evaluated as part of the uncertainty assessment for their respective fish feeding guilds.

[b] Unbounded LOAEL TRV.

[c] FFS total TEQ HQs are based on the sum of PCB and PCDD/PCDF TEQ EPCs; appropriate total TEQ HQs are based on EPCs calculated by CPG

Figure 7. Other Fish Tissue LOAEL HQs

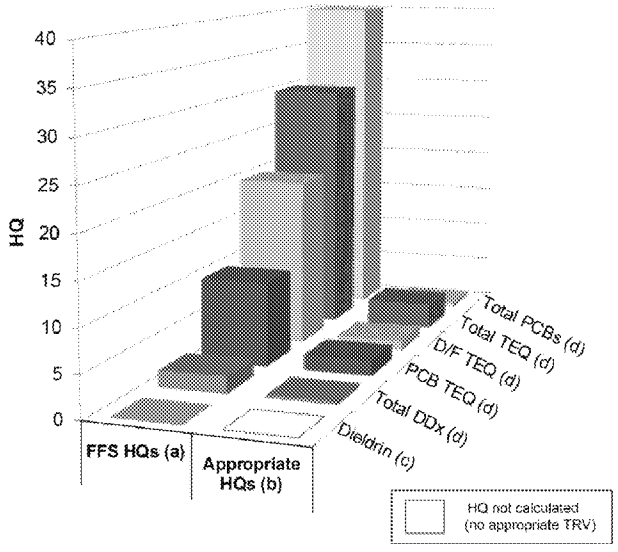


[a] FFS LOAEL HQs as reported in Table 4-17 of Appendix D. FFS HQs for mummichog assumes embryo lipid of 8.2% based on lake trout (Cook et al. 2003) and whole body lipid of 1.9% based on LPRSA mummichog. FFS HQs for generic fish assumes embryo lipid of 8.2% based on lake trout (Cook et al. 2003) and whole body lipid of 5.9% based on LPRSA American eel and white perch.

[b] Appropriate LOAEL HQs based on EPCs based on site-specific and species appropriate lipid values (see specific comments) and CPG recommended TRVs (see Table 8). Appropriate HQs for mummichog assumes embryo lipid of 3.1% and whole body lipid of 1.9% based on LPRSA mummichog.

[c] Modeling a "generic" fish embryo concentrations on the generic fish EPC is inappropriate.

Figure 8. Fish Embryo LOAEL HQs



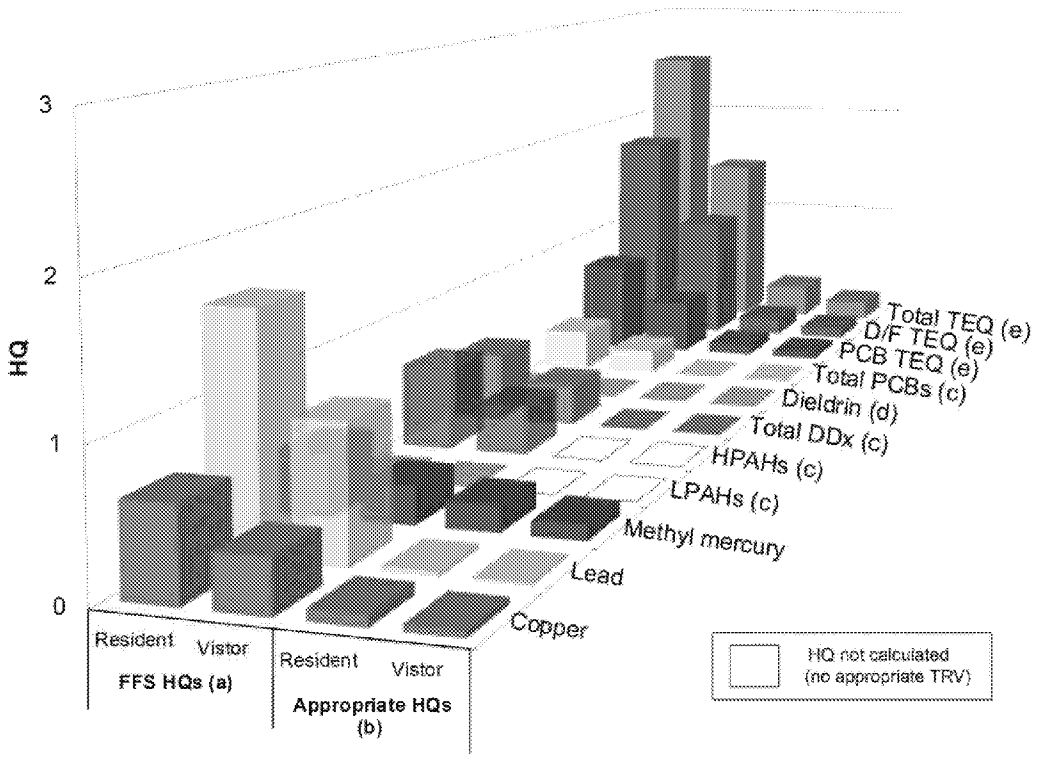
[a] FFS LOAEL HQs as reported in Table 4-18 of Appendix D. FFS HQs assume embryo lipid of 7.7% based on herring gull and fish lipid of 5.9% based on generic fish samples from lower 8.3 miles of LPR.

[b] Appropriate LOAEL HQs based on EPCs based on receptor-specific lipid values, EPCs based on appropriately-sized prey (mummichog; Table 3), receptor-specific BMFs, and CPG recommended TRVs (see Table 9). Appropriate HQs assume embryo lipid of 5.7% based on great blue heron and fish lipid of 1.2% based on mummichog samples from lower 8.3 miles of LPR.

[c] Only a NOAEL TRV is recommended.

[d] Unbounded LOAEL TRV.

Figure 9. Avian Embryo LOAEL HQs



[a] FFS LOAEL HQs based on mummichog/crab diet as reported in Table 4-19 of Appendix D.

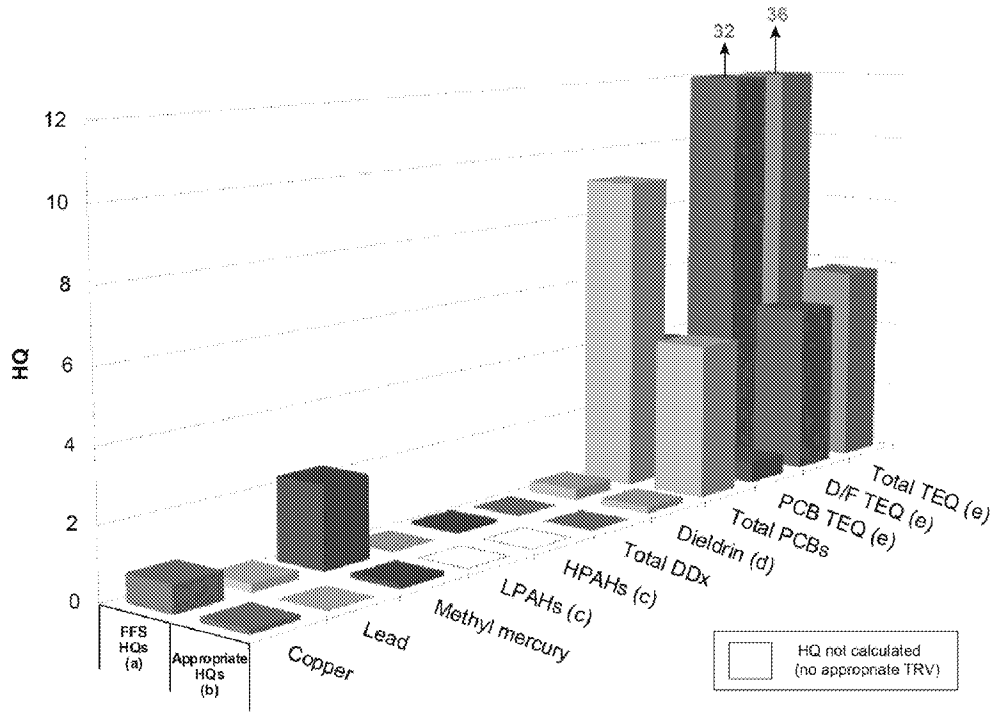
[b] Appropriate LOAEL HQs based on doses calculated from mummichog and blue crab EPCs as presented in FFS, corrected dry weight sediment ingestion rate (SIR) of 0.0051 kg dw/day using site-specific moisture content for fish and blue crab (74%), and sediment EPCs based on additional mudflat data not included in the FFS EPCs. Visitor dose was calculated with FFS exposure duration (ED) of 0.58; resident dose was calculated with an ED of 1. HQs calculated with appropriate TRVs (see Table 10).

[c] Unbounded NOAEL or LOAEL TRV

[d] FFS TRVs for dieldrin are only appropriate as screening-level values (see Table 10).

[e] FFS total TEQ HQs are based on the sum of PCB and PCDD/PCDF TEQ EPCs; appropriate total TEQ HQs are based on EPCs calculated by CPG.

Figure 10. Heron Dietary LOAEL HQs



[a] FFS LOAEL HQs as reported in Table 4-19 of Appendix D.

[b] Appropriate LOAEL HQs based on doses calculated with fish EPCs based on appropriately sized fish tissue (i.e., fish < 30 cm), blue crab EPCs as presented in the FFS, a corrected dry weight sediment ingestion rate (SIR) of 0.00088 kg dw/day using site-specific moisture content for fish and blue crab (74%) and sediment EPCs calculated with additional available sediment data that was not included in the FFS. HQs calculated with appropriate TRVs (see Table 11).

[c] CPG recommends evaluating individual PAHs in mammal diet rather than total LPAH/HPAHs. No individual PAHs are expected to have HQs > 1 based on the entire 17.4 LPRSA SLERA using the screening-level TRVs presented in Windward ([in prep]-I).

[d] FFS TRVs for dieldrin are only appropriate as screening-level values (see Table 11).

[e] FFS total TEQ HQs are based on the sum of PCB and PCDD/PCDF TEQ EPCs; appropriate total TEQ HQs are based on EPCs calculated by CPG.

Figure 11. Mink Dietary LOAEL HQs

21. An evaluation of background concentrations is absent from risk characterization, which is out of compliance with EPA guidance (USEPA 2002b).

Section 4.4: Risk Characterization. The evaluation of background concentrations should be included in the risk characterization section per EPA guidance (USEPA 2002b). "*Specifically, the COPCs with high background concentrations should be discussed in the risk characterization, and if data are available, the contribution of background to site concentrations should be distinguished.*" (USEPA 2002b). For the LPR, in agreement with Region 2, the chemistry data available in existing regional data sets in freshwater and estuarine areas from Delaware Bay to southern New England were evaluated to determine if these data were sufficient and appropriate to define a regional background data set for the LPR. These data sources were evaluated to define regional background consistent with USEPA's (2002b) definition of "constituents or locations that are not influenced by the releases from a site but represent an influence on the site." Following a review of the existing data sets compiled by the CPG, USEPA (2013) selected the following areas to represent a range of background conditions for the LPR:

- The Passaic River above Dundee Dam (freshwater data from an urban habitat)
- Jamaica Bay (estuarine data from an urban habitat)
- Mullica River (including Great Bay) (estuarine data from an rural habitat)

While the PRG appendix (Appendix E) discusses a subset of background data from above Dundee Dam (but models background tissue data rather than using the empirical tissue data collected from above Dundee Dam), the ERA fails to consider background data as part of risk characterization. Furthermore, the FFS fails to acknowledge existing estuarine tissue and sediment background data from regional areas that were identified by USEPA (2013) for the LPR risk assessments.

22. The FFS ERA fails to integrate multiple LOEs to arrive at overall ecological risk conclusions.

Section 4.4: Risk Characterization, p. 4-44. Each LOE is evaluated independently of one another and generic risk conclusions are made based on the individual risk estimates (Section 4.4). The multiple LOEs (i.e., fish tissue and fish egg) are not integrated to support risk conclusions for each receptor group. Furthermore, a discussion of the implications of the hazard estimates for community- and population-level effects for each receptor group is not provided. As stated in USEPA (1997), "*for ecological risk assessments that entail more than one type of study (or line of evidence), a strength-of-evidence approach is used to integrate different types of data to support a conclusion. The data might include toxicity test results, assessments of existing impacts at a site, or risk calculations comparing exposures estimated for the site with toxicity values from the literature. Balancing and interpreting the different types of data can be a major task and require professional judgment. As indicated above, the strength of evidence provided by different types of tests and the precedence that one type of study might have over another should already have been established during Step 4. Taking this approach will ensure that data interpretation is objective and not biased to support a preconceived answer. Additional strength-of-evidence considerations at this stage include the degree to which DQOs were met and whether confounding factors became evident during the site investigation and analysis phase.*"

Section 4.4: Risk Characterization, p. 4-44 and Tables 4-15 through 4-19. 1. Summing of HQs (derivation of hazard indices) has little ecological relevance. Summing all HQs to calculated a hazard index (HI) for all COPECs per receptor is not appropriate for interpreting the results of the risk characterization because it weights all HQs equally regardless of ecological relevance or significance. While it is stated that the BERA "*predominantly focuses on the results for individual COPECs or chemical classes*" and the inherent uncertainty in applying the HI approach atypically (i.e., for chemicals with different toxic mechanisms and effects that are not necessarily synergistic or additive) is acknowledged, HIs remain the basis for the remedial alternatives future risk assessment in Section 5, the results of which are intended to be a risk management tool. This is an oversimplified approach that obscures a number of uncertainties associated with individual risk estimates.

Section 4.4: Risk Characterization, p. 4-44. Risk conclusions do not clearly identify contaminants of concern. No contaminants of concern (COCs) are clearly identified for any receptor group. In accordance with USEPA guidance (USEPA 1999), ecological COCs should be identified. In the summary and conclusions section of Appendix D (Section 6.2.1), there is a limited discussion of COPECs determined to have the "greatest hazards". Based on this discussion, COCs could be identified as all COPECs for benthic invertebrates, TCDD (D/F) TEQ, copper, and total PCBs for fish, total TEQ for birds, and PCB TEQ for mammals. It would be more appropriate to focus on COCs in the assessment of remedial alternatives rather than continuing to include COPECs for which there is no estimated risk.

Table 4-18. Total TEQ NOAEL HQ is incorrect and does not match Table 5-4 in Attachment 5. NOAEL HQ should be 70 and not 80.

Table 4-19. Table does not indicate that the mercury HQs are actually based on methylmercury concentrations, not total mercury. Table footnote lettering is out of order within the table (e.g., the callout for footnote a is missing within the table; footnote b is referenced multiple times in the wrong place).

23. The discussion of specific uncertainties associated with the selected CBRs/TRVs is incomplete and overly general, masking the assumptions that were used to derive risk estimates.

Section 4.5: Ecological Uncertainty Analysis, p. 4-51. According to USEPA (1998): "*Risk assessors need to clearly describe any uncertainties associated with the ecological response analysis. If it was necessary to extrapolate from measures of effect to the assessment endpoint, both the extrapolation and its basis should be described. Similarly, if a benchmark or similar reference dose or concentration was calculated, the extrapolations and uncertainties associated with its development need to be discussed…Finally, the assessor should clearly describe major assumptions and default values used in the models.*" The FFS uncertainty discussion is very general (abundant use of "generally" and "typically" without providing specific examples) and does not tie in results of the risk characterization (e.g., HQ magnitude). Specific discussion of the relevance and appropriateness of individual benchmarks/CBRs/TRVs should be addressed, including uncertainty associated with selected TRVs, such as field-based studies, co-contaminated prey, relevance of chemical form use in exposure, etc. In addition, only the use of a 10-fold extrapolation factor to calculate a NOAEL is discussed; other uncertainty factors are not mentioned (e.g., interspecies and acute/subchronic-to-chronic UFs).

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